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Tal et al.

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(54) **INFUSION CATHETERS AND RELATED SYSTEMS AND METHODS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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US 2024/0050642 A1 Feb. 15, 2024

Related U.S. Application Data

(63) Continuation of application No. 17/367,838, filed on Jul. 6, 2021, now abandoned, which is a continuation
(Continued)

(51) **Int. Cl.**
A61M 25/10 (2013.01)
A61M 5/14 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 5/14*** (2013.01); ***A61M 25/003*** (2013.01); ***A61M 25/0052*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61M 25/003; A61M 25/0075; A61M 25/104
See application file for complete search history.

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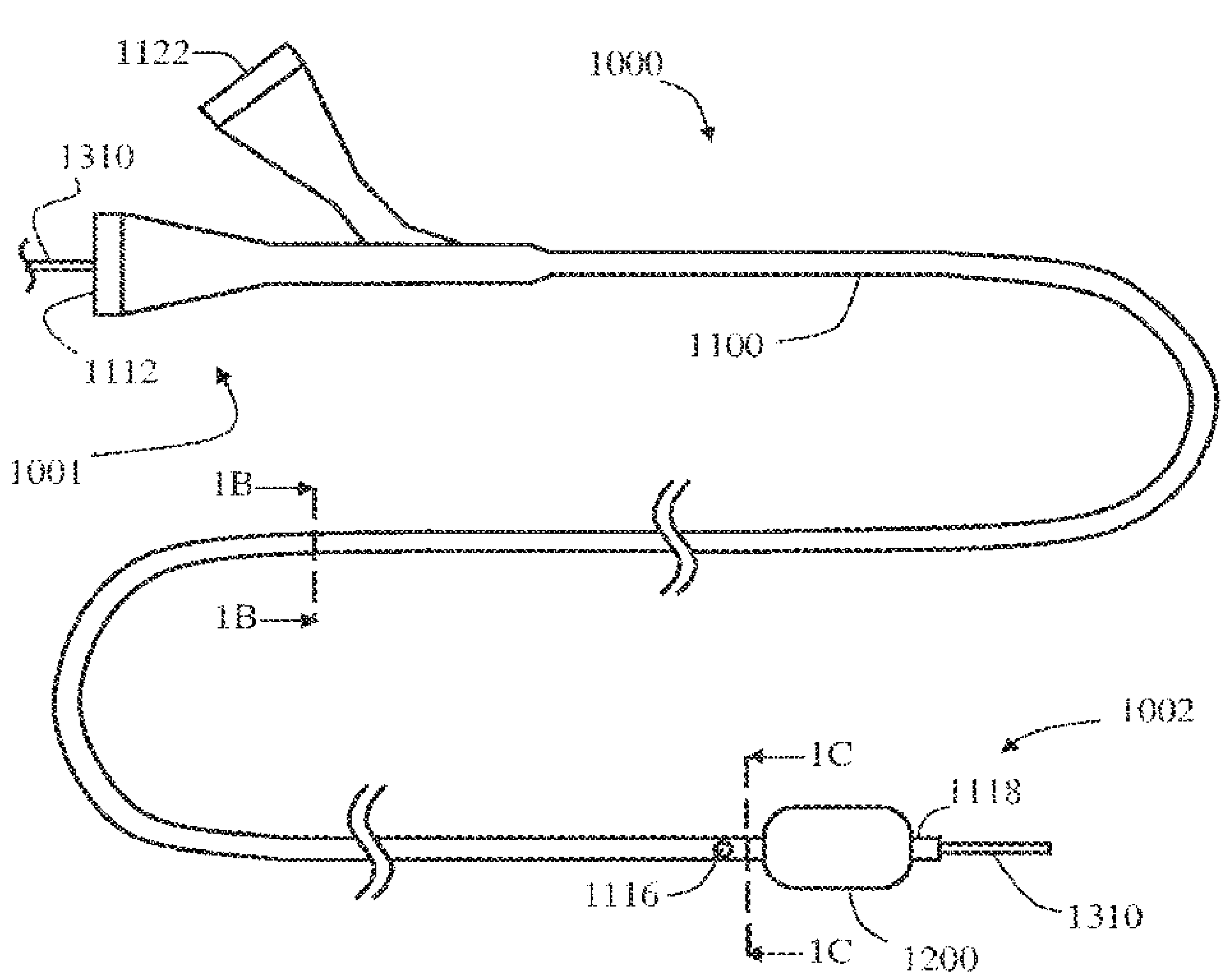
(57) **ABSTRACT**

Double-lumen infusion catheter including: a shaft having proximal section, distal section, and intermediate section therebetween; first and second lumens extending along a length of the shaft and having arc shaped wall therebetween; and an inflatable member provided distally to intermediate section, and over the distal section. First lumen has cross section larger than cross section of second lumen and is configured to receive a guidewire therethrough and allow fluid flow via an unobstructed portion of first lumen. Unobstructed portion is formed along guidewire outer surface, between guidewire outer surface and inner wall of first lumen, and extends from an inlet at proximal end of intermediate section to an outlet at distal end of intermediate section. First lumen is narrowed to approximate a first diameter in shaft proximal and distal sections, and is widened to approximate a second diameter greater than first diameter in the shaft intermediate section.

15 Claims, 14 Drawing Sheets



Related U.S. Application Data

of application No. 15/430,776, filed on Feb. 13, 2017, now Pat. No. 11,052,188, which is a continuation of application No. 14/760,774, filed as application No. PCT/US2014/010752 on Jan. 8, 2014, now Pat. No. 10,363,358.

(60) Provisional application No. 61/752,649, filed on Jan. 15, 2013.

(51) **Int. Cl.**
A61M 25/00 (2006.01)
A61M 25/09 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 25/0075*** (2013.01); ***A61M 25/008*** (2013.01); ***A61M 25/09041*** (2013.01); ***A61M 25/104*** (2013.01); *A61M 2025/0018* (2013.01); *A61M 2025/0076* (2013.01); *A61M 2025/0079* (2013.01); *A61M 2025/0081* (2013.01); *A61M 2025/091* (2013.01); *A61M 2025/1052* (2013.01); *A61M 2210/12* (2013.01)

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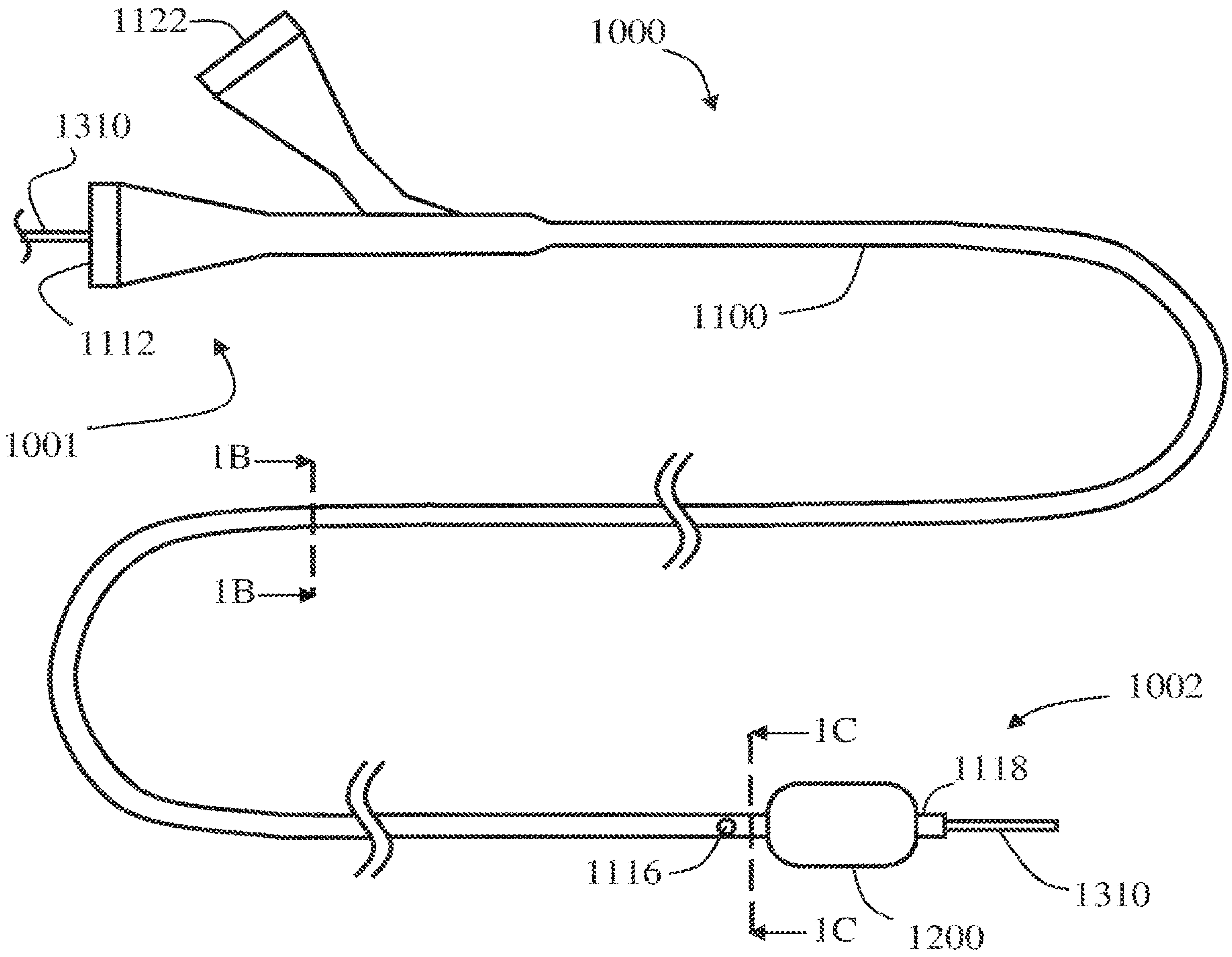


FIG 1A

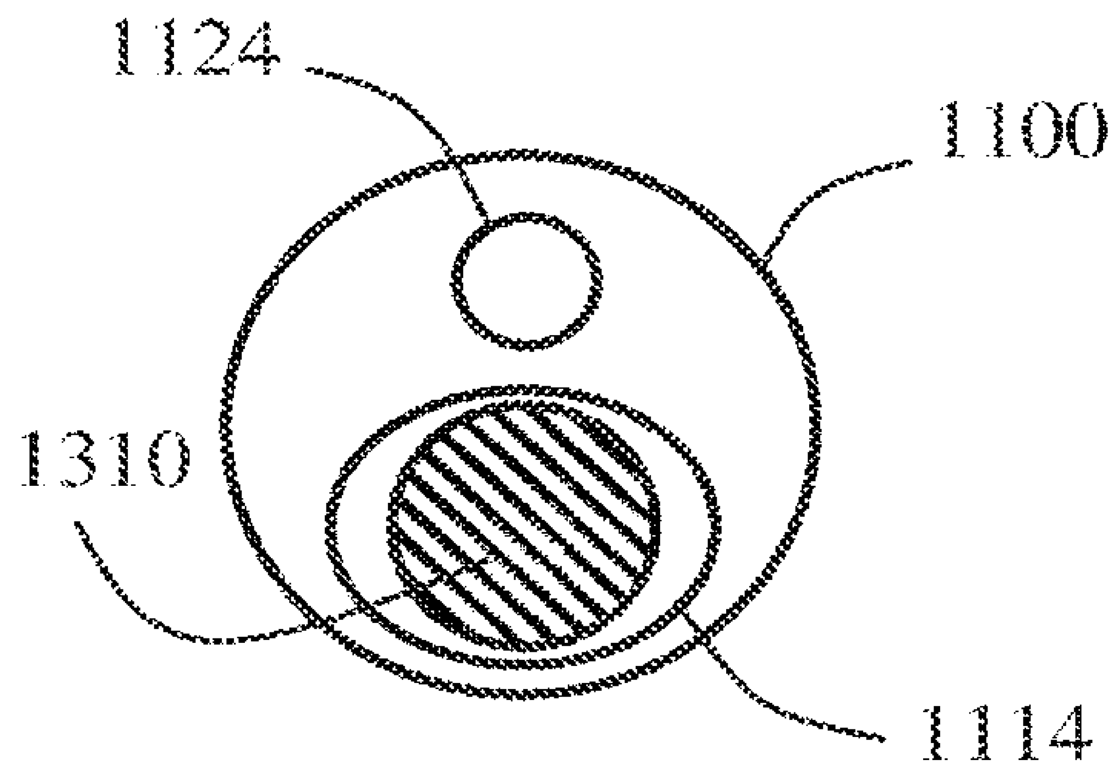


FIG 1B

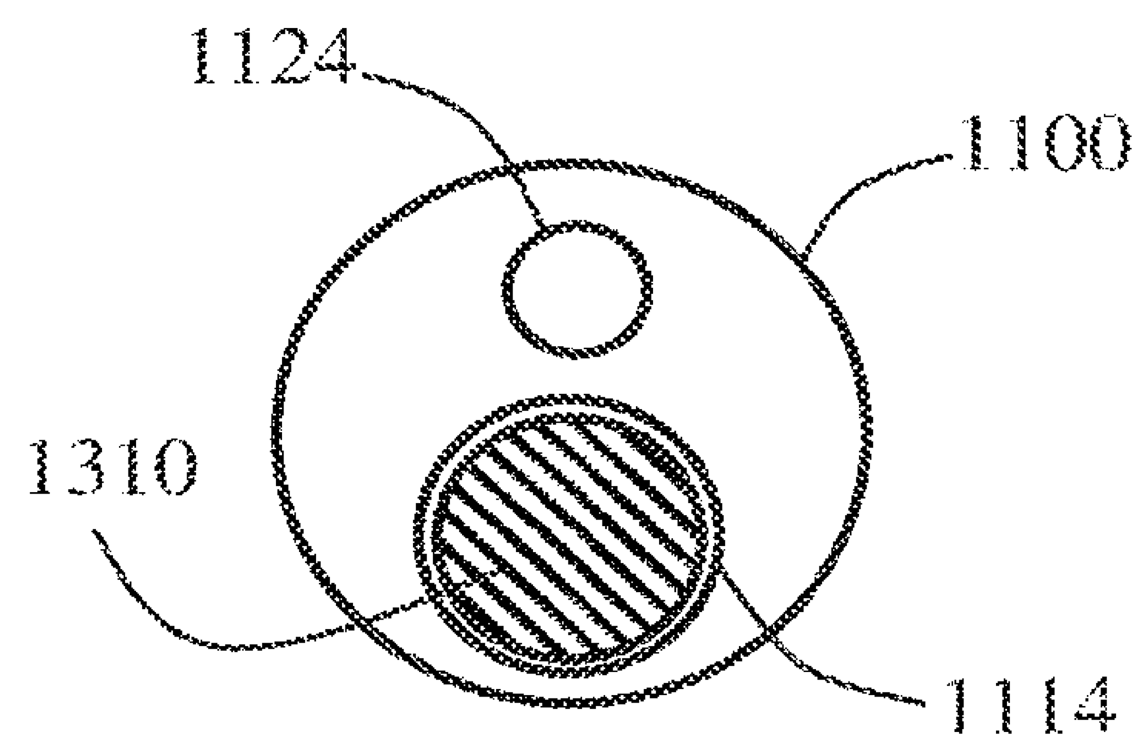


FIG 1C

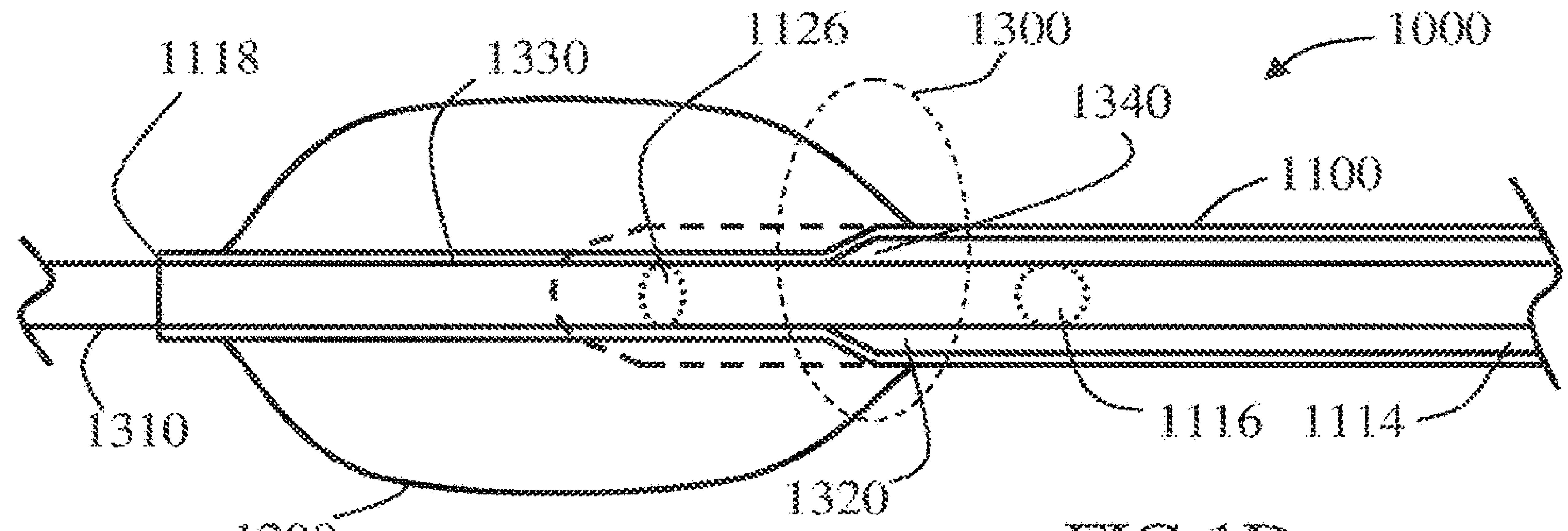


FIG 1D

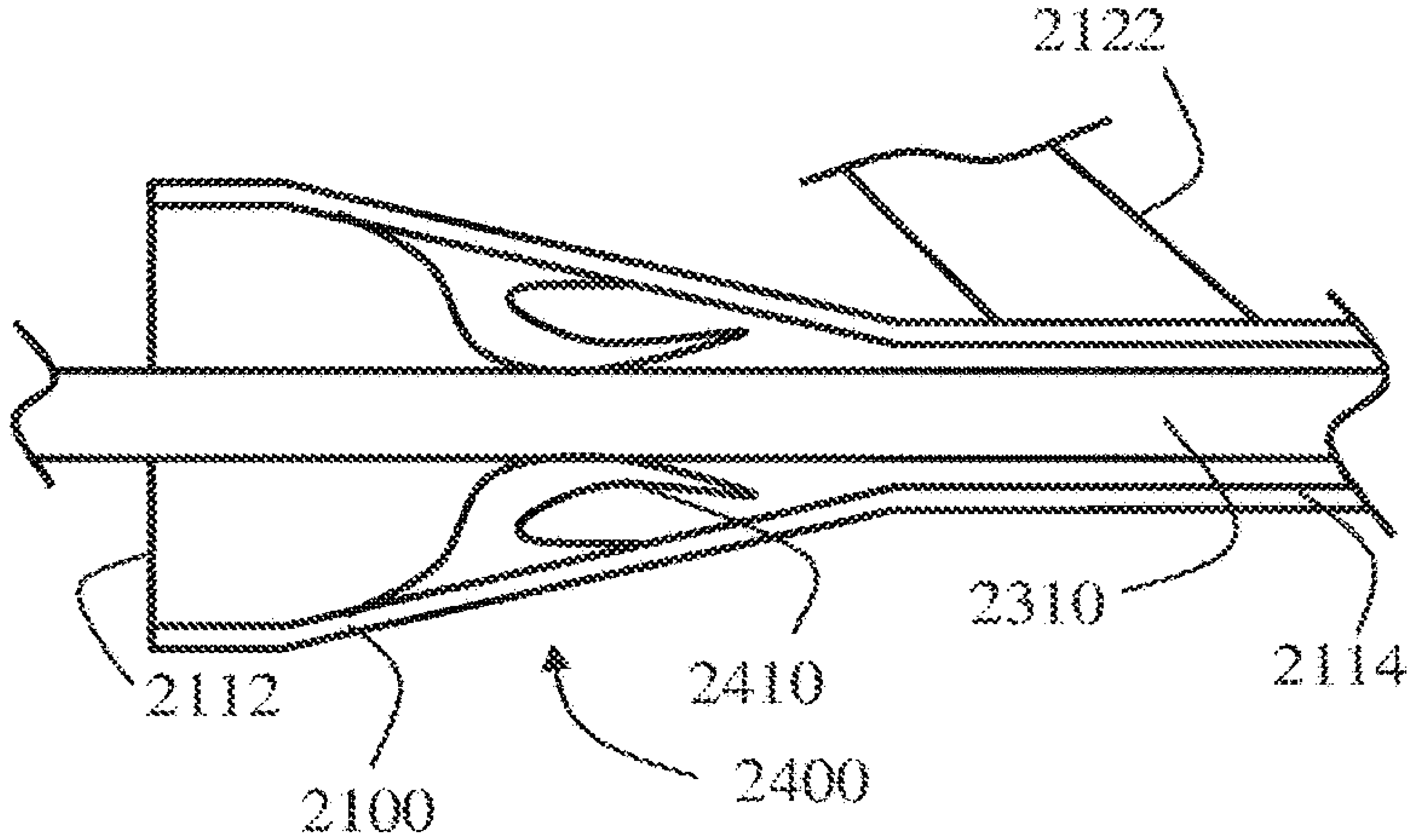


FIG 2A

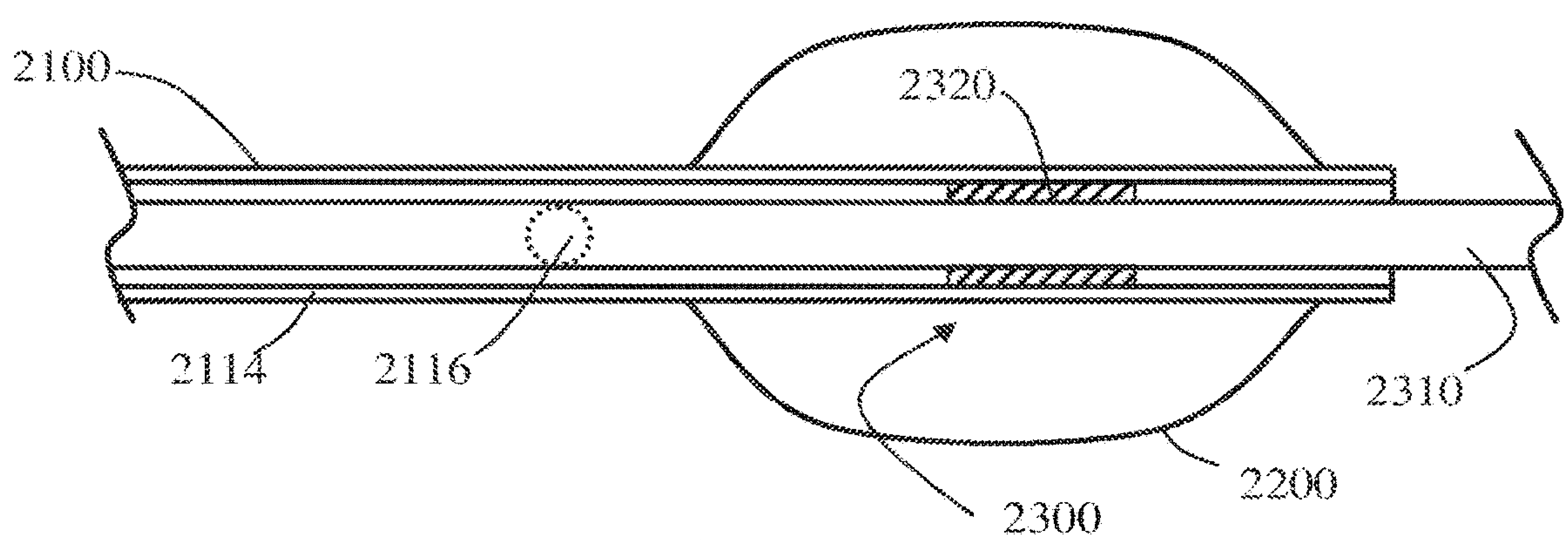


FIG 2B

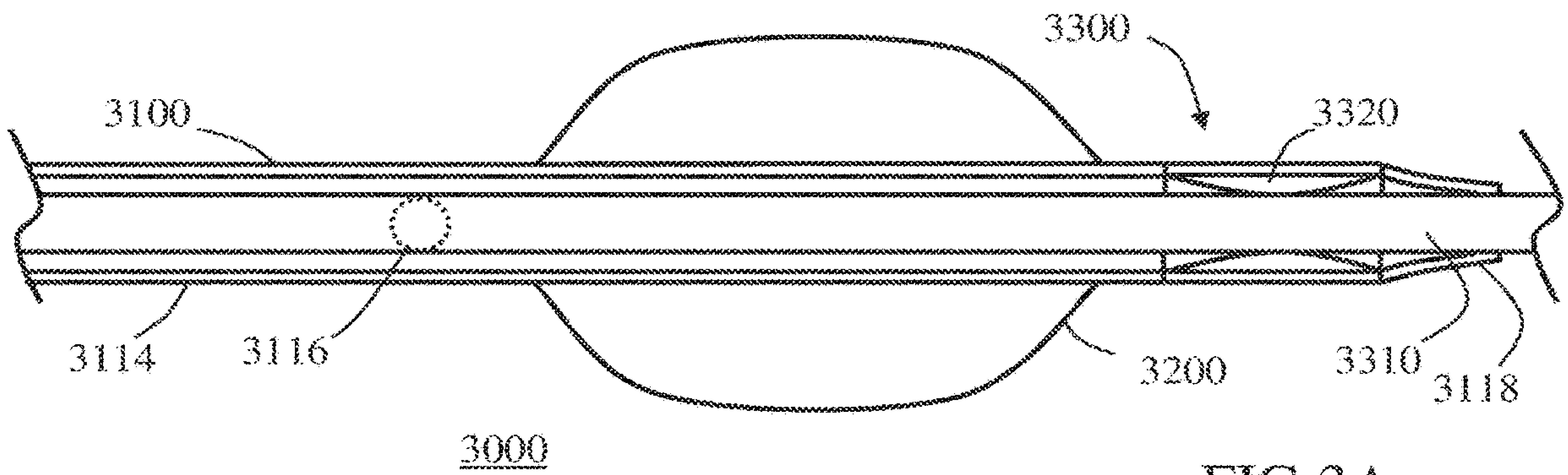


FIG 3A

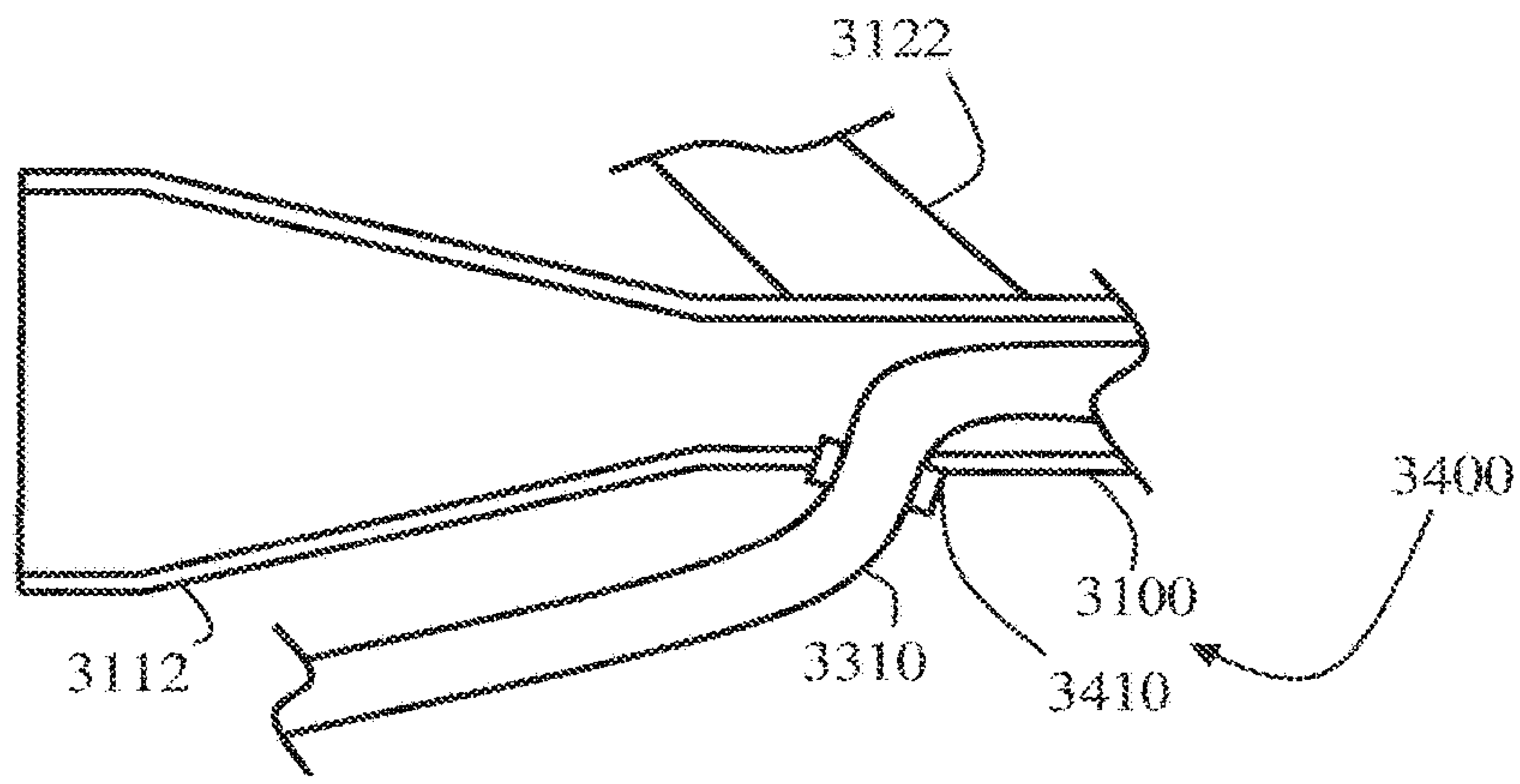


FIG 3B

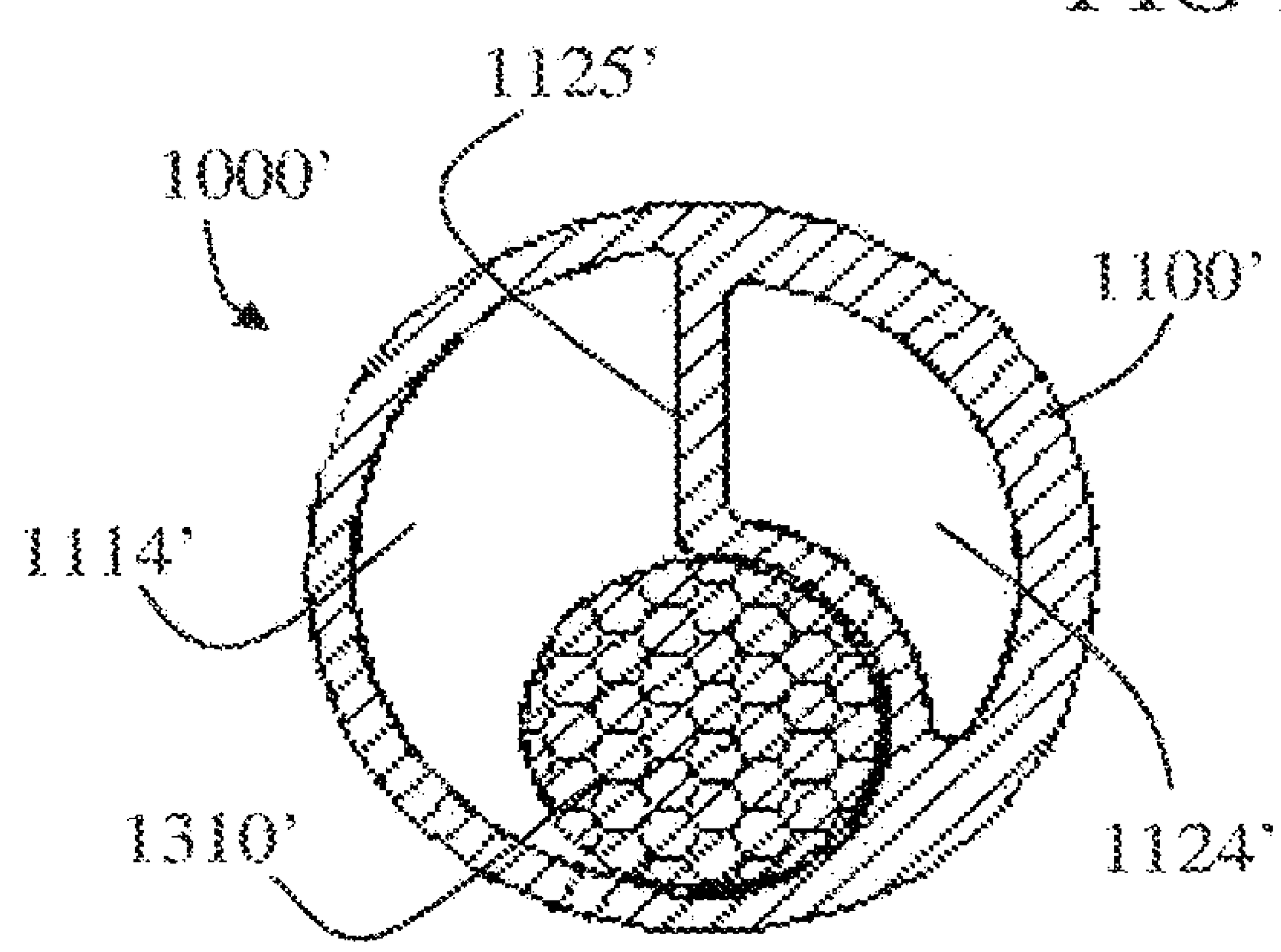


FIG 4A

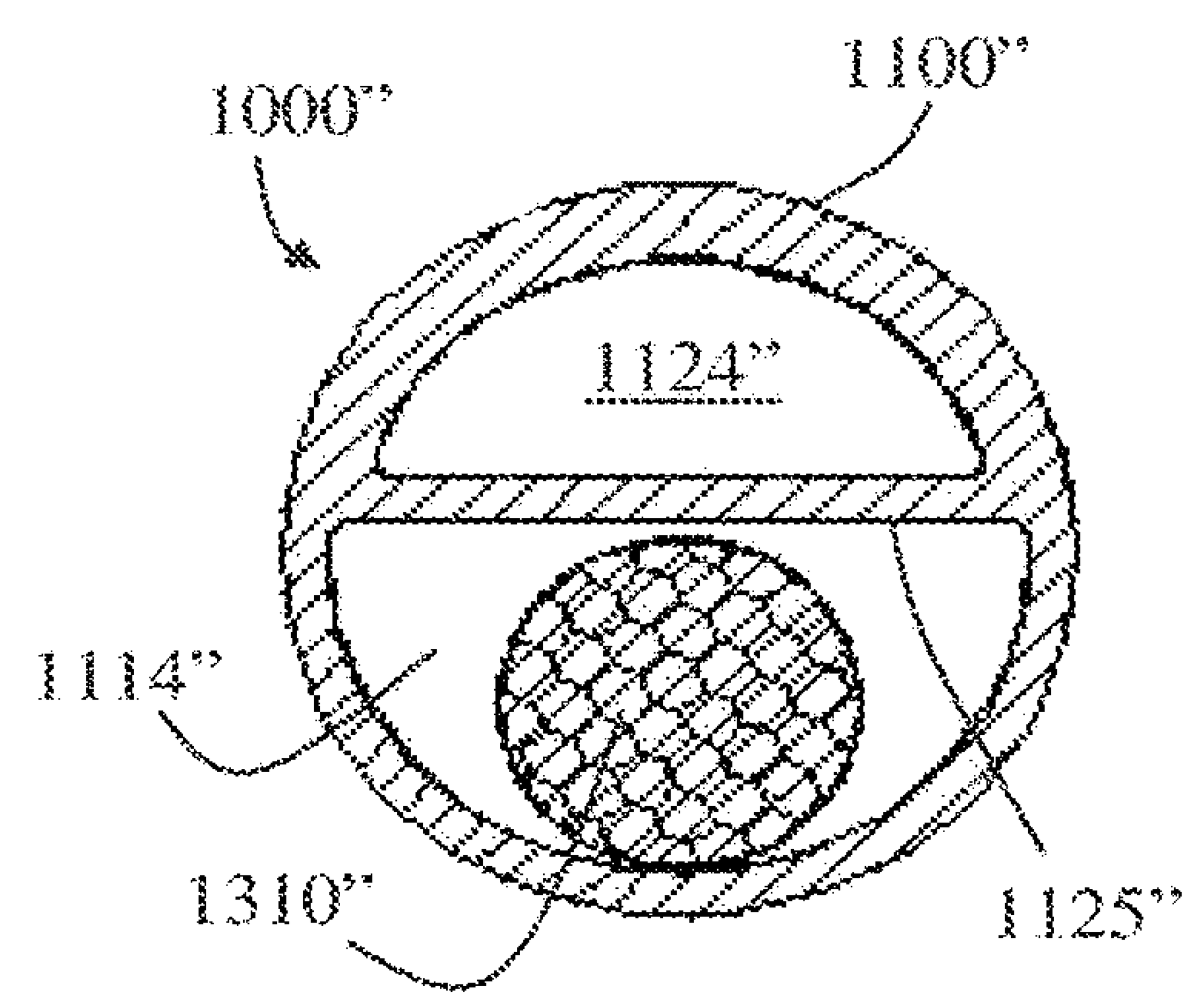


FIG 4B

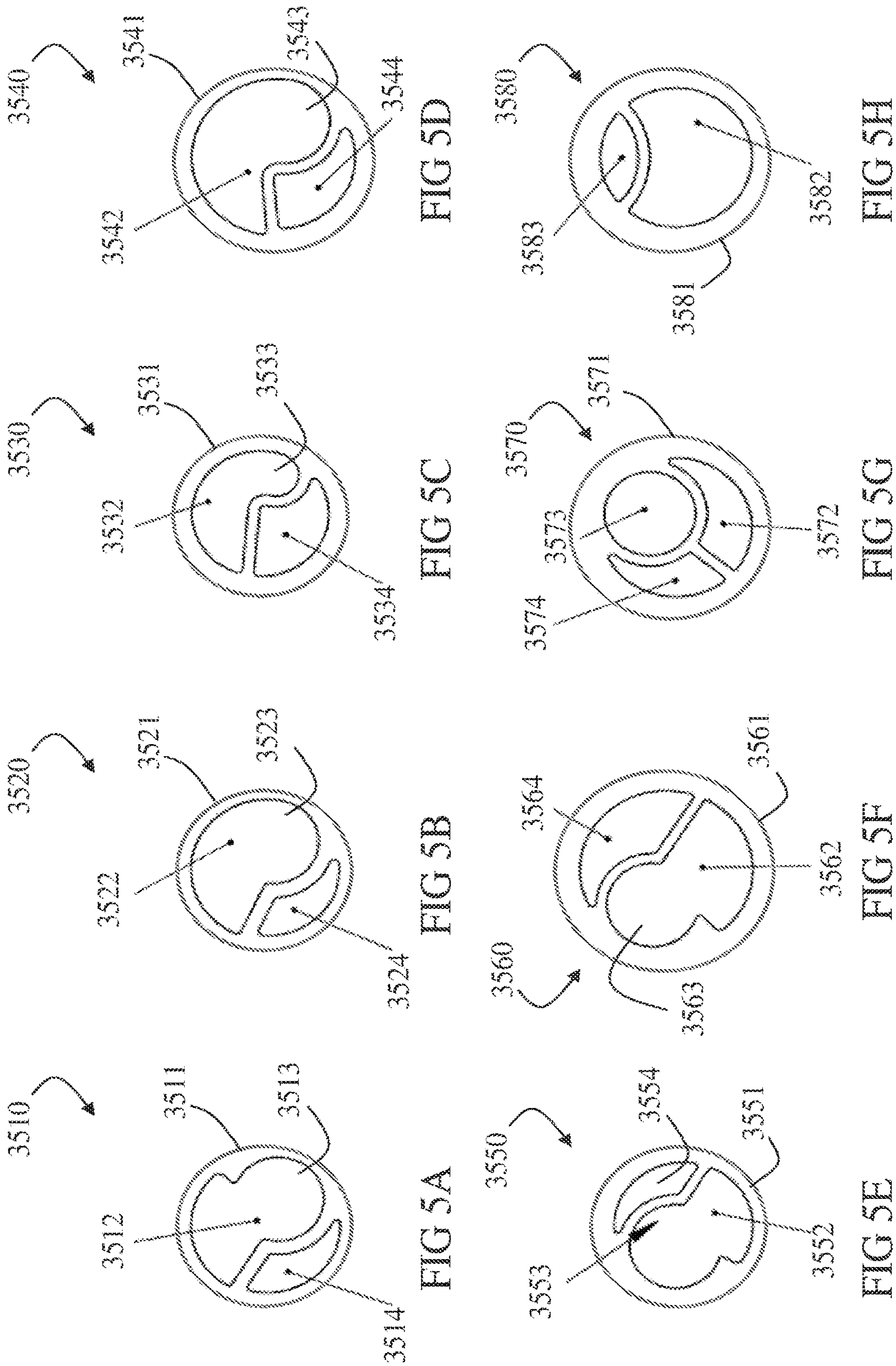


FIG 5A

FIG 5B

FIG 5C

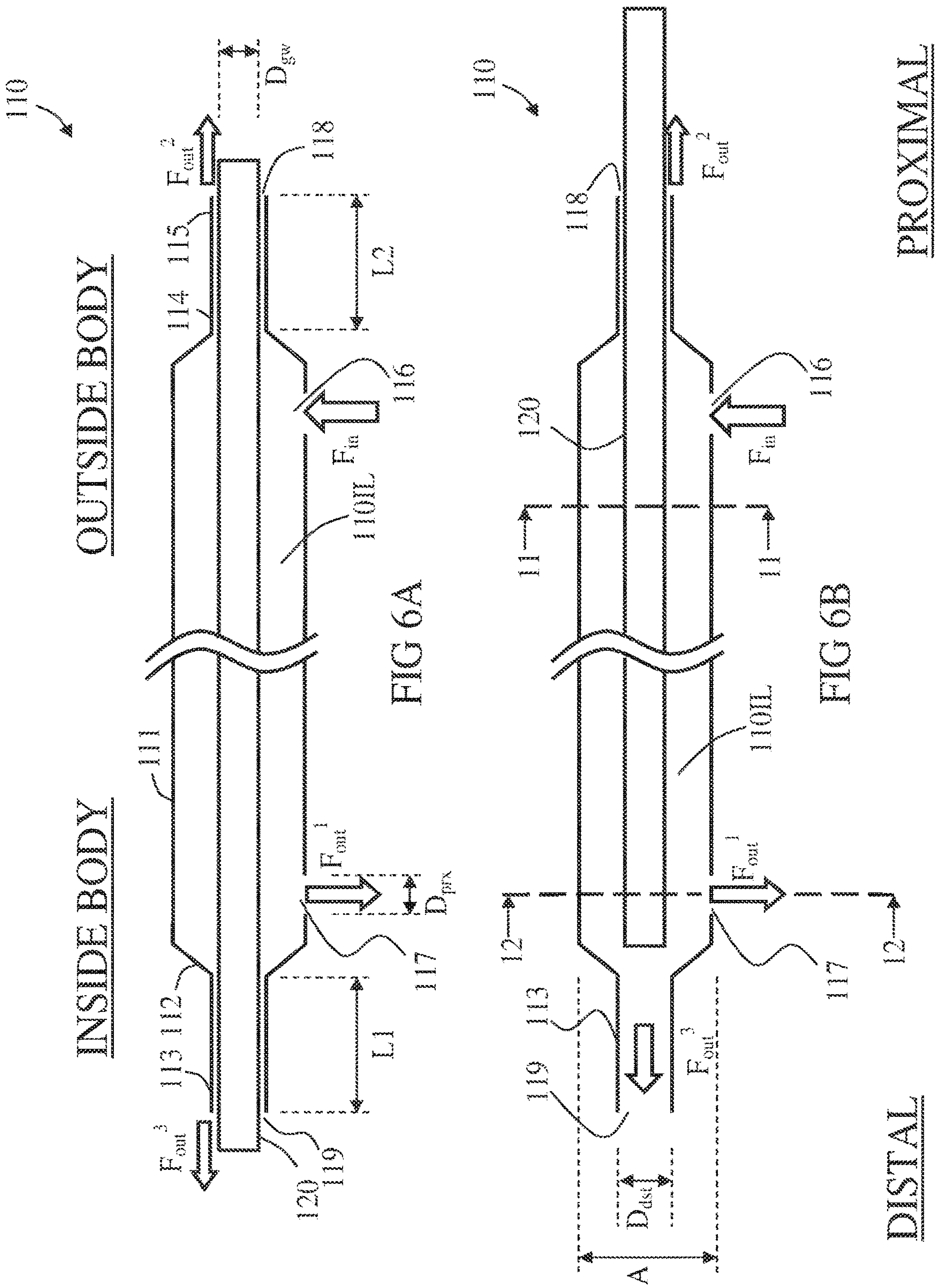
FIG 5D

FIG 5E

FIG 5F

FIG 5G

FIG 5H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INSIDE BODY
PROXIMAL
DISTAL
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112
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116
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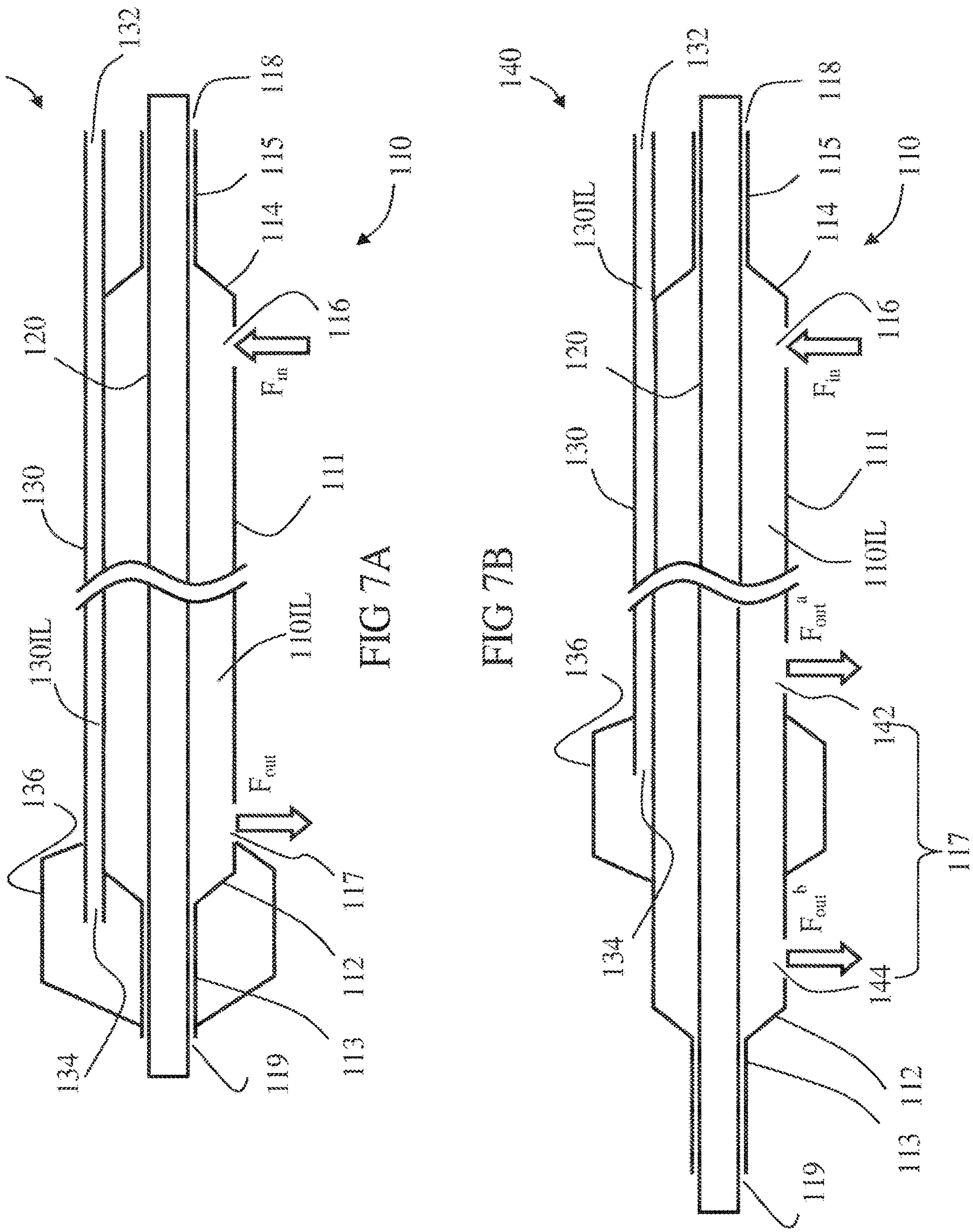
110IL
L1
L2
A
11
12

FIG 6A

FIG 6B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134
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132
118
115
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130IL
114
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F_{in}
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F_{out}^{b}
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113
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FIG 7A

FIG 7B

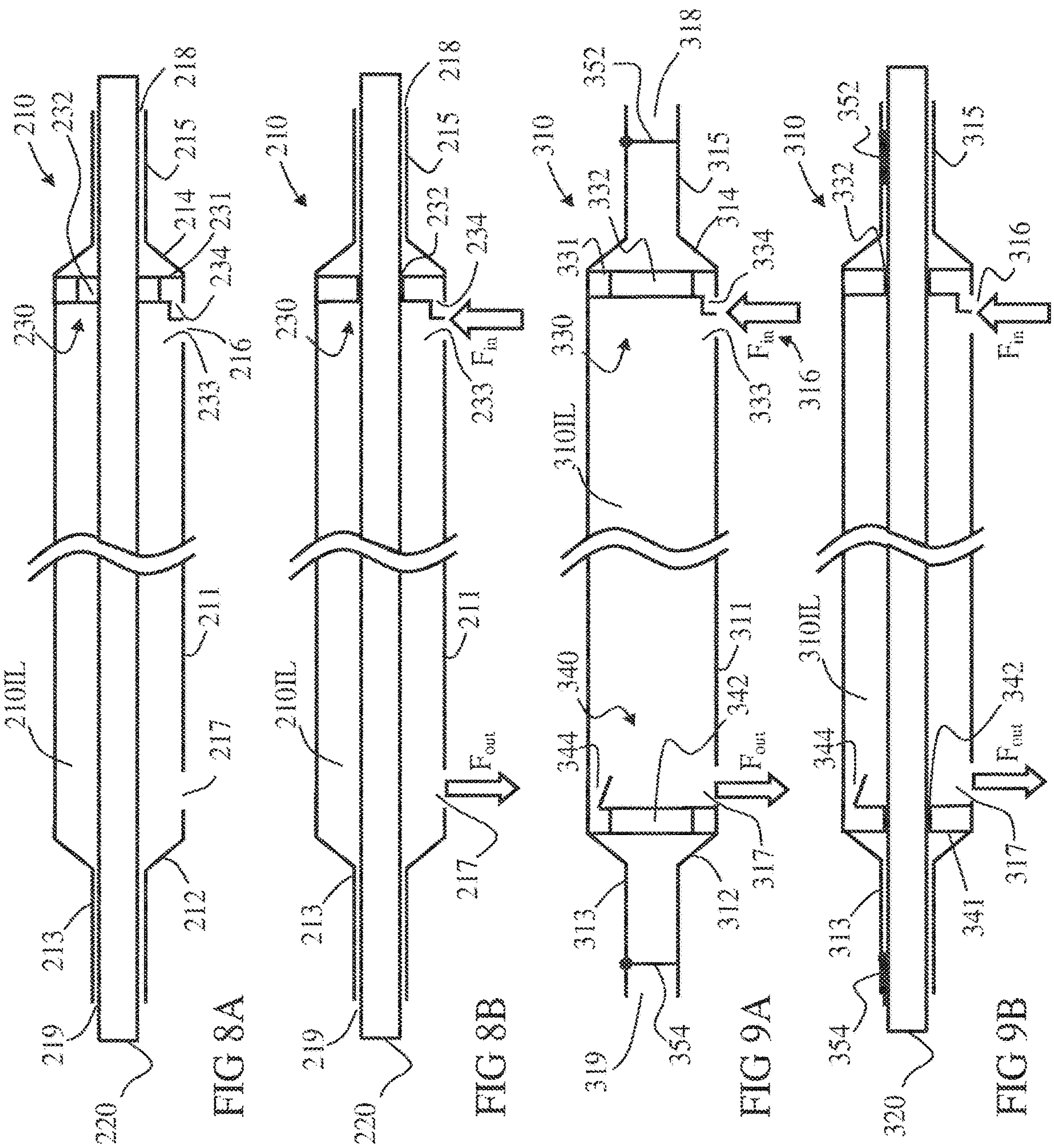


FIG 8A

FIG 8B

FIG 9A

FIG 9B

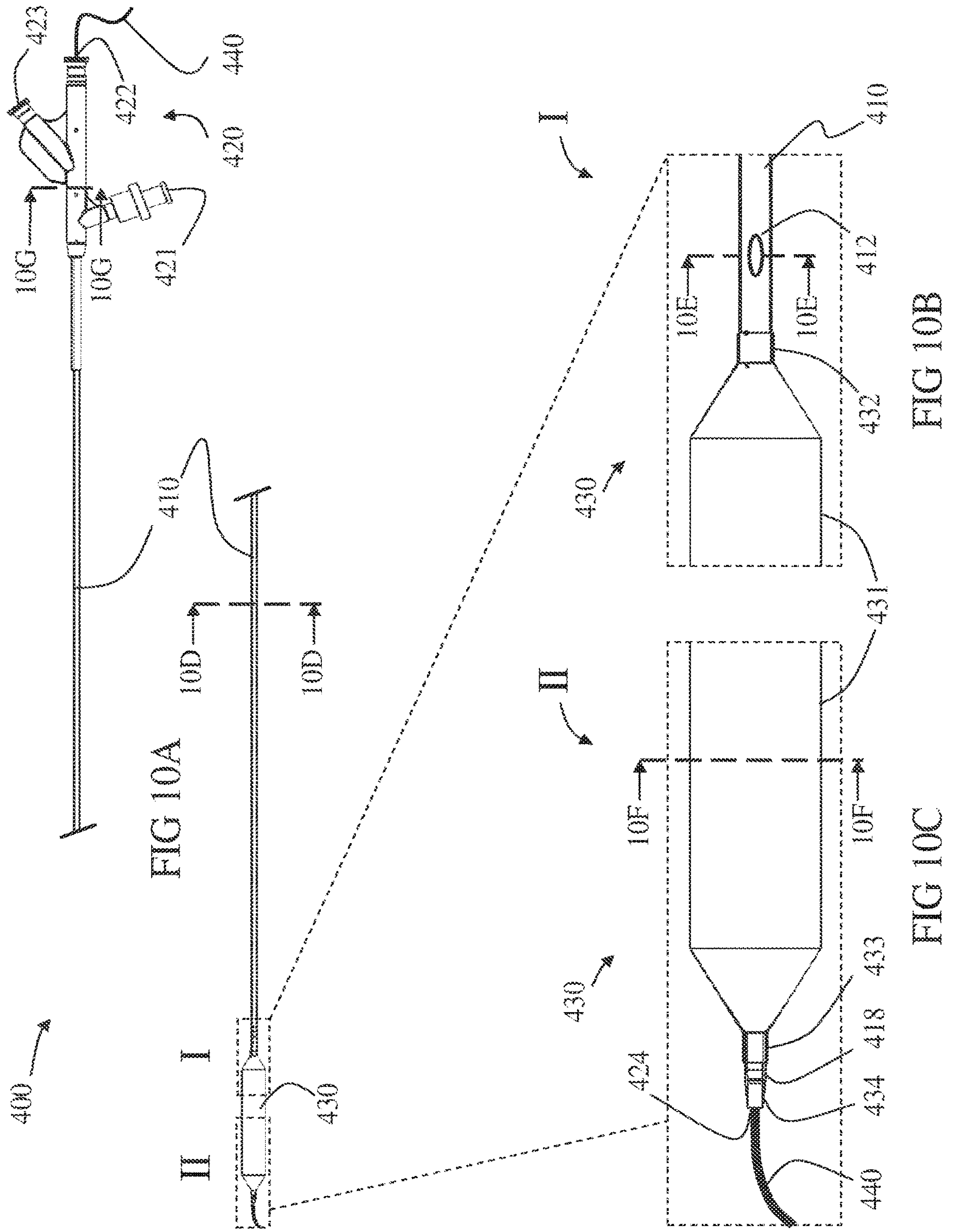


FIG 10A

FIG 10B

FIG 10C

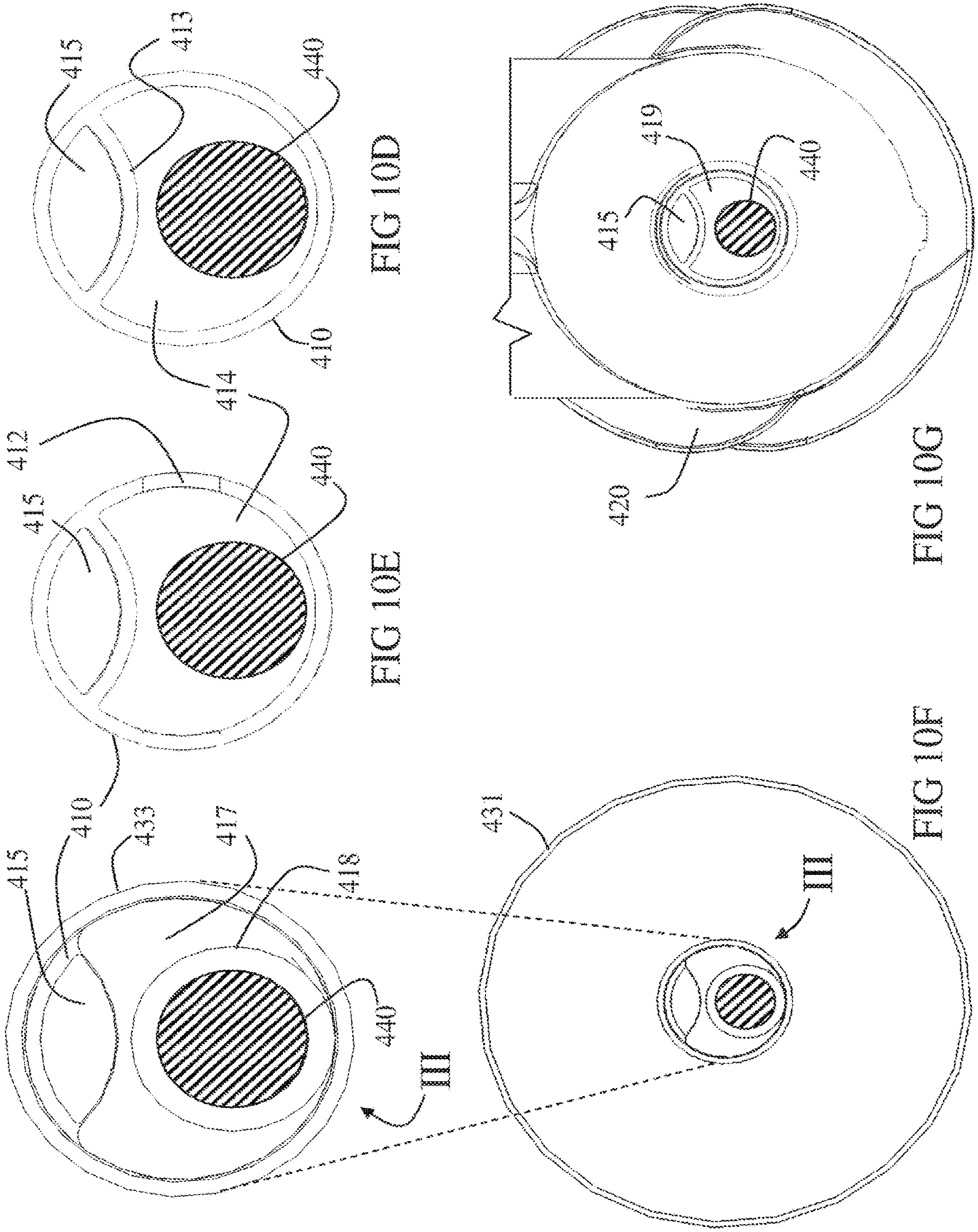


FIG 10D

FIG 10E

FIG 10F

FIG 10G

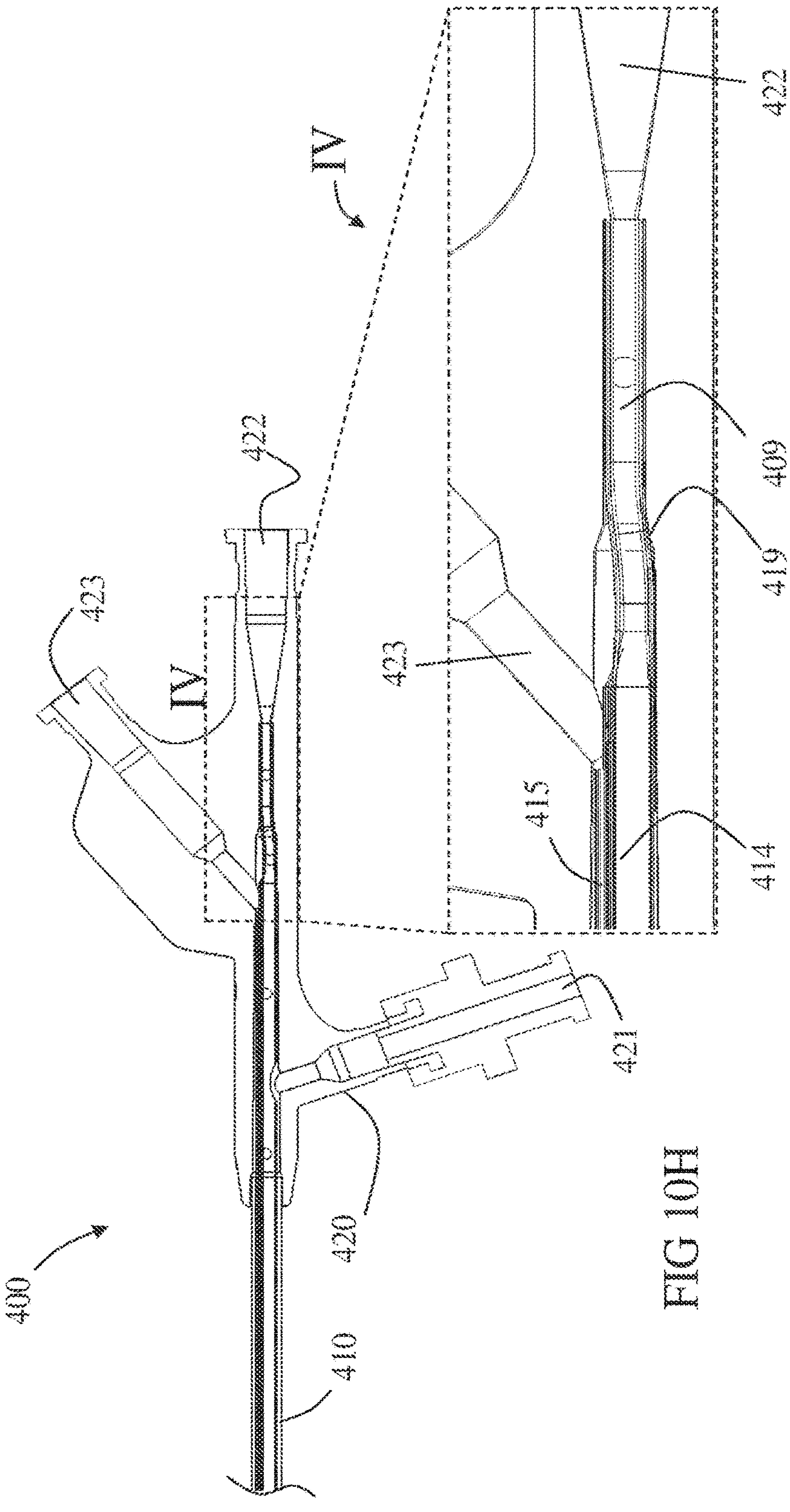


FIG 10H

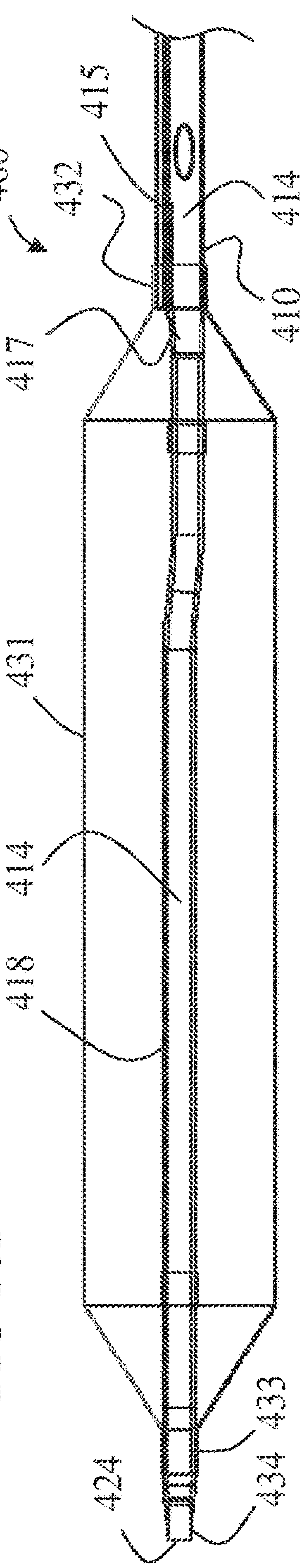


FIG 10I

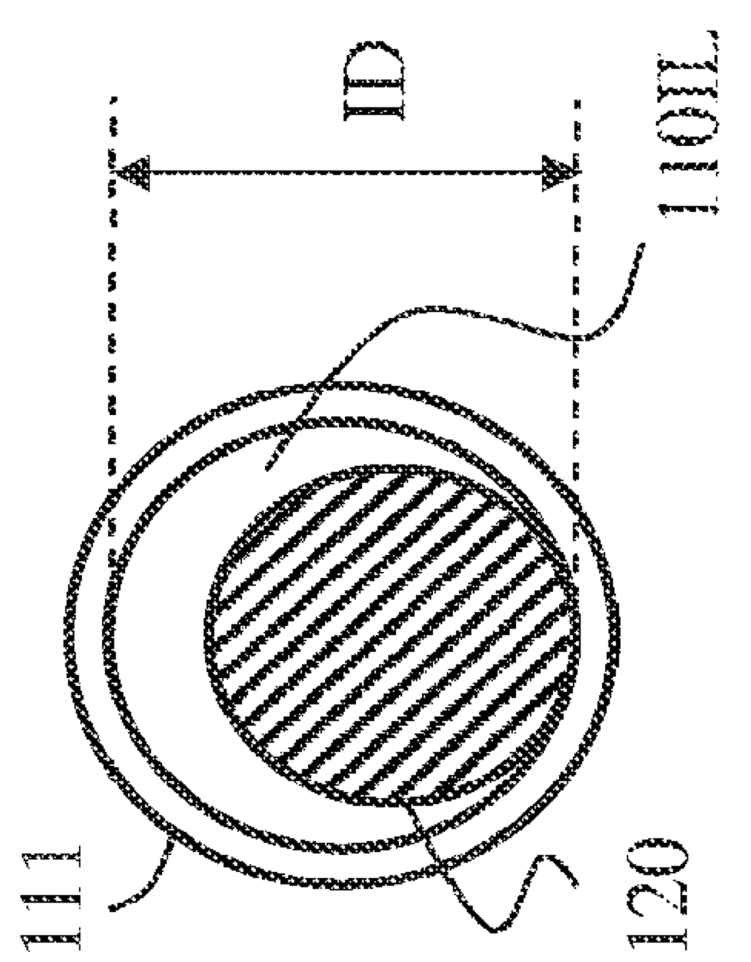


FIG 11A

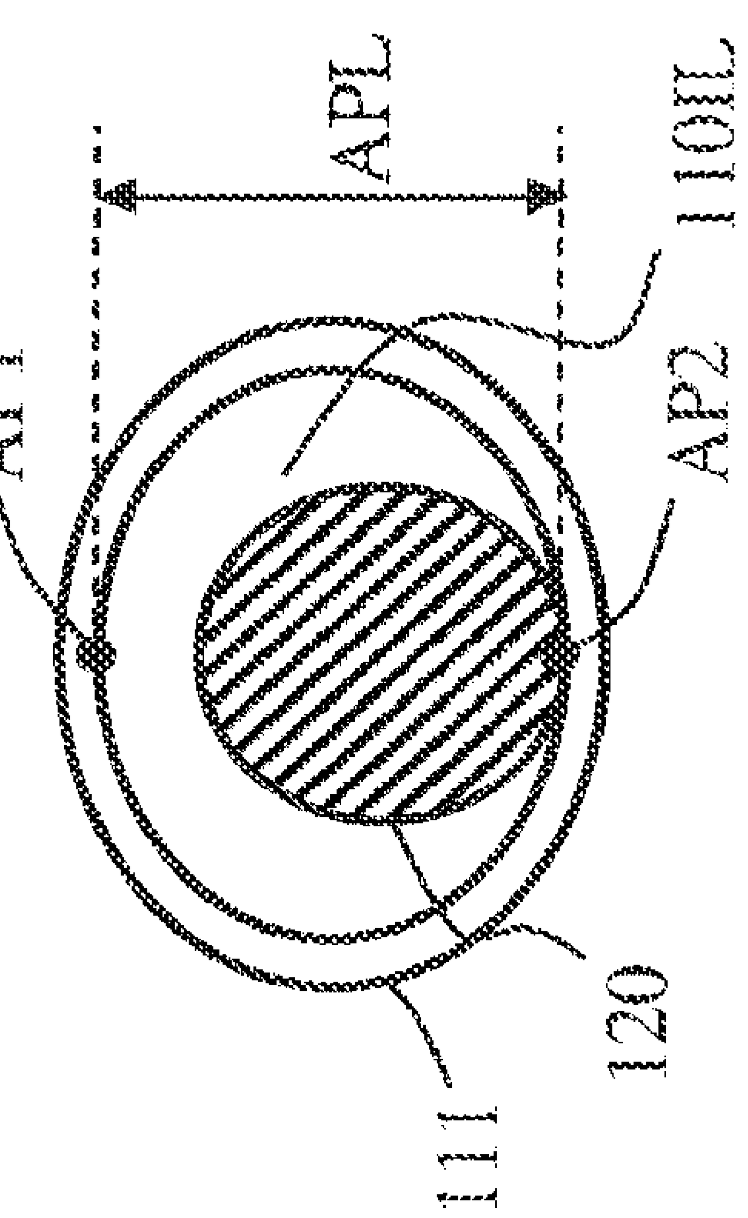


FIG 11B

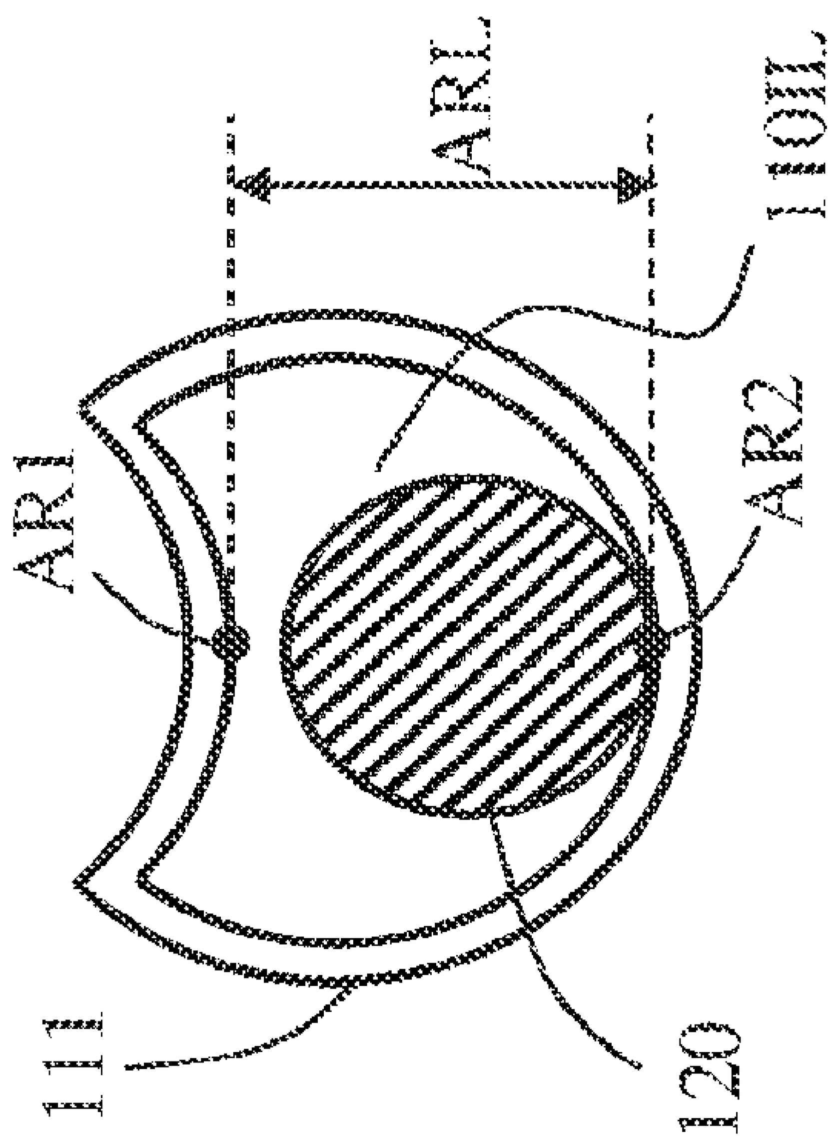


FIG 11C

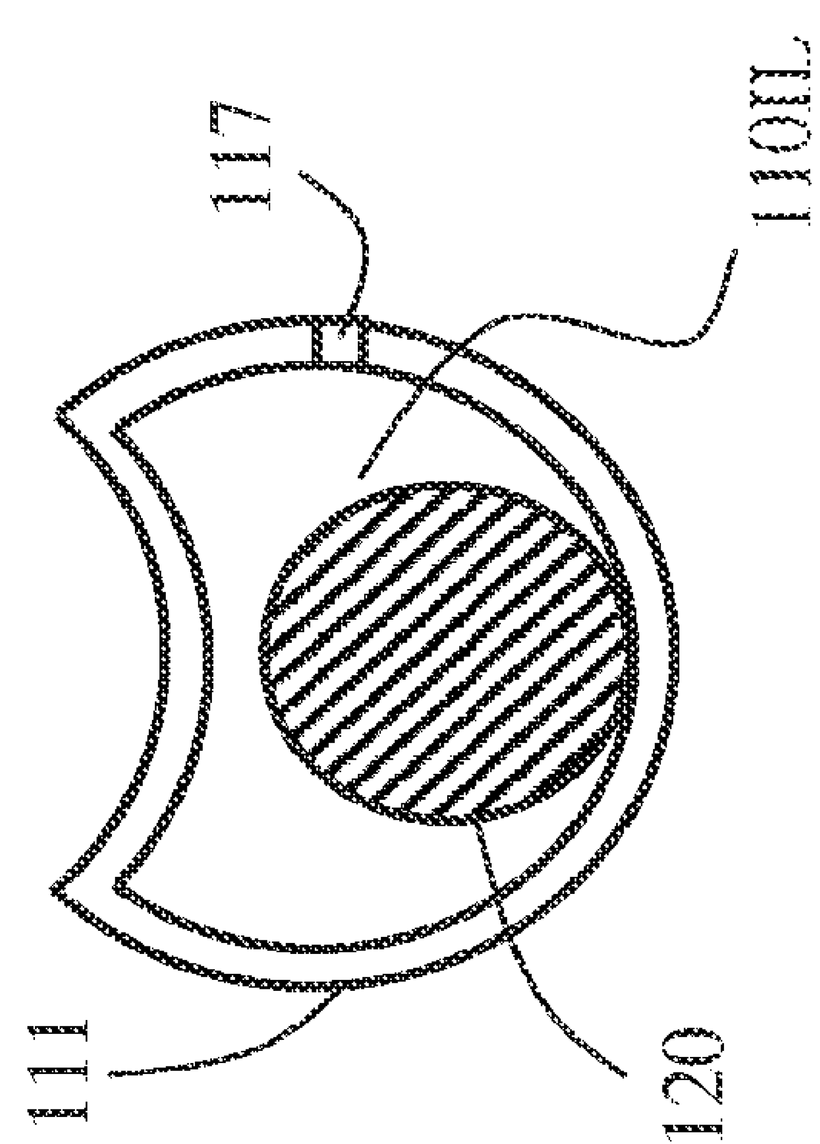
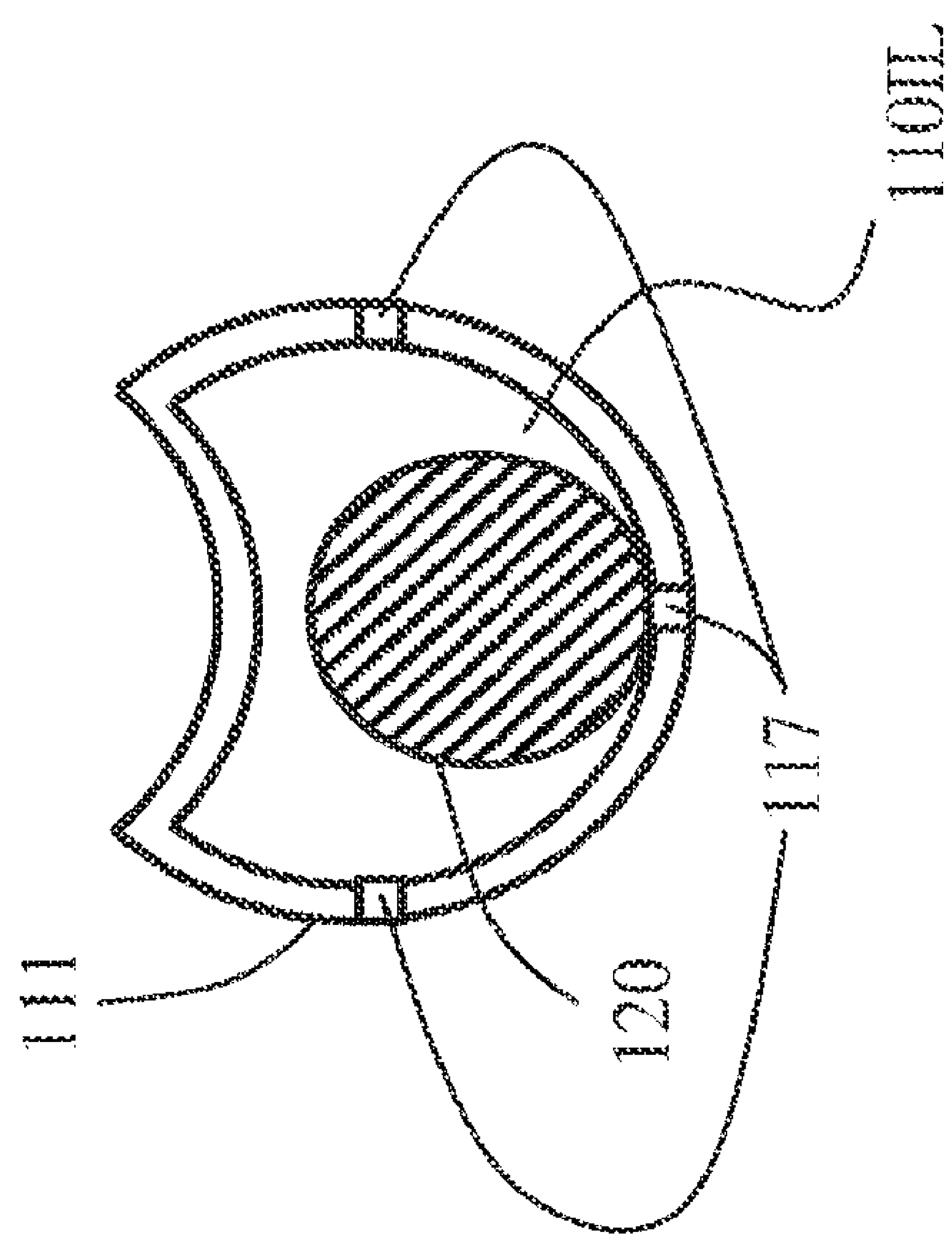


FIG 12A



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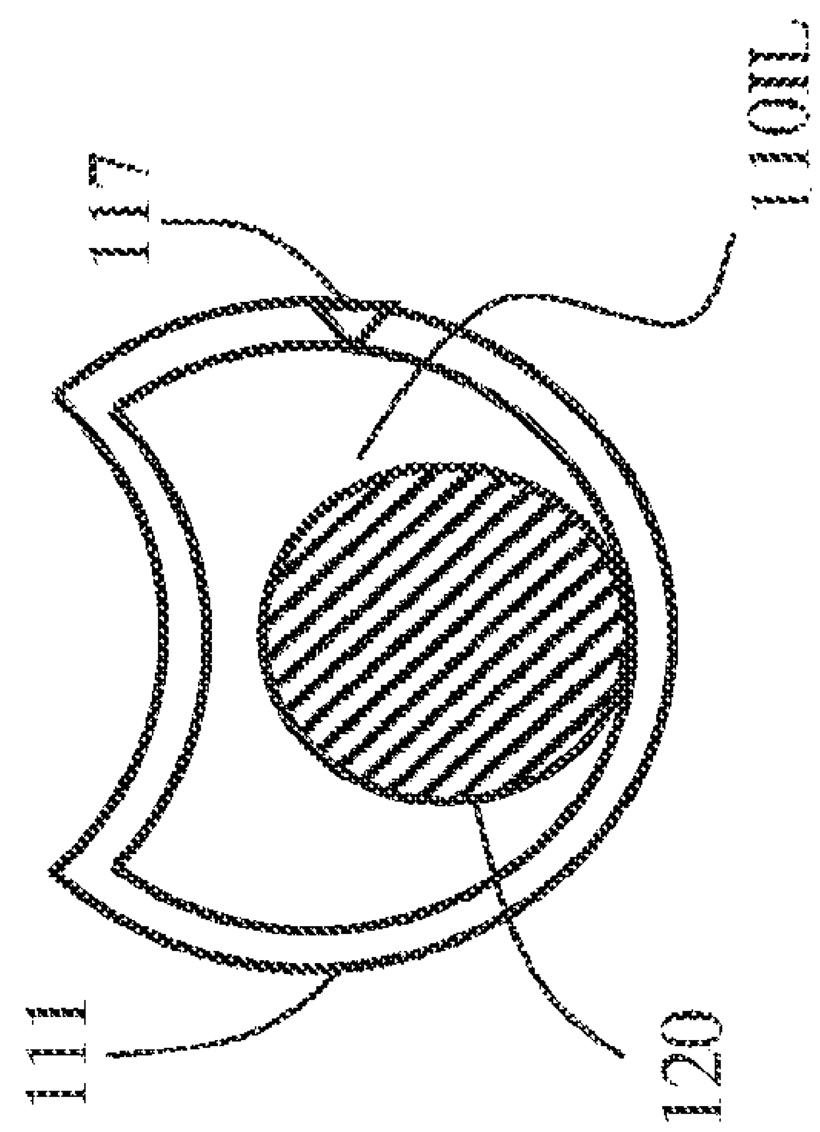


FIG 12C

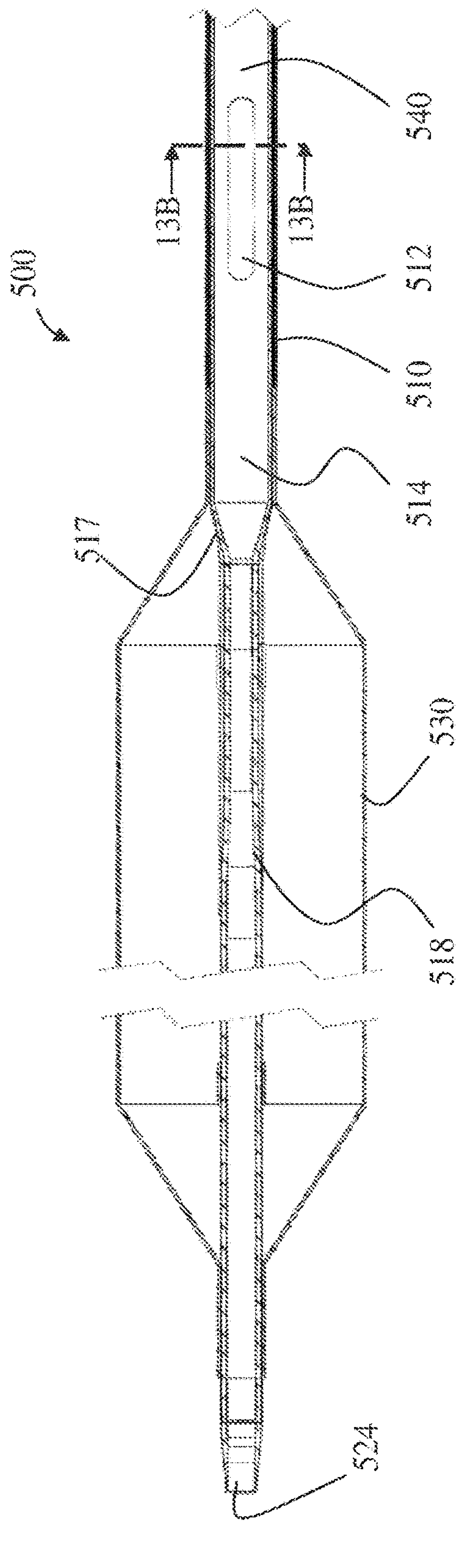
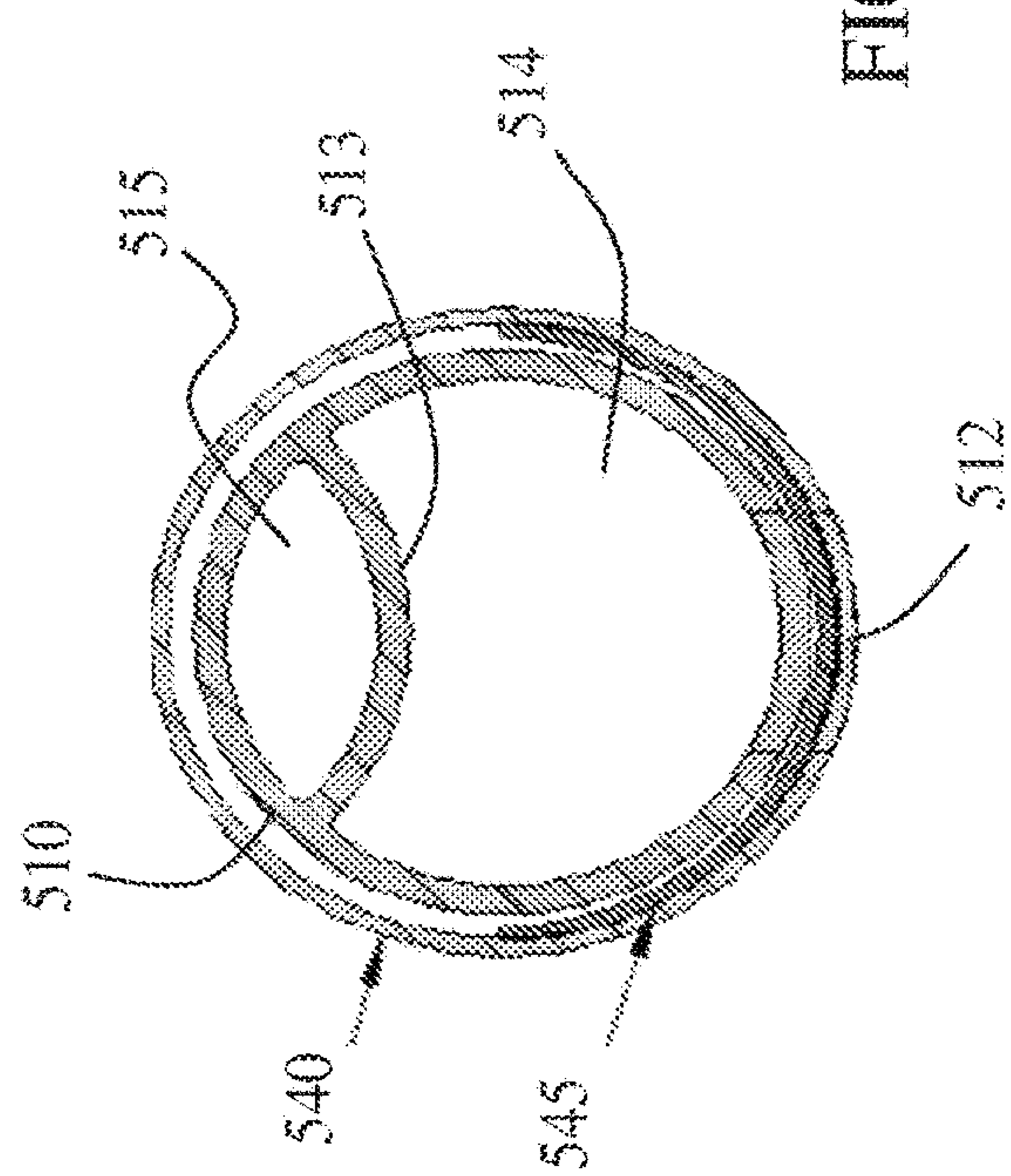


FIG 13A



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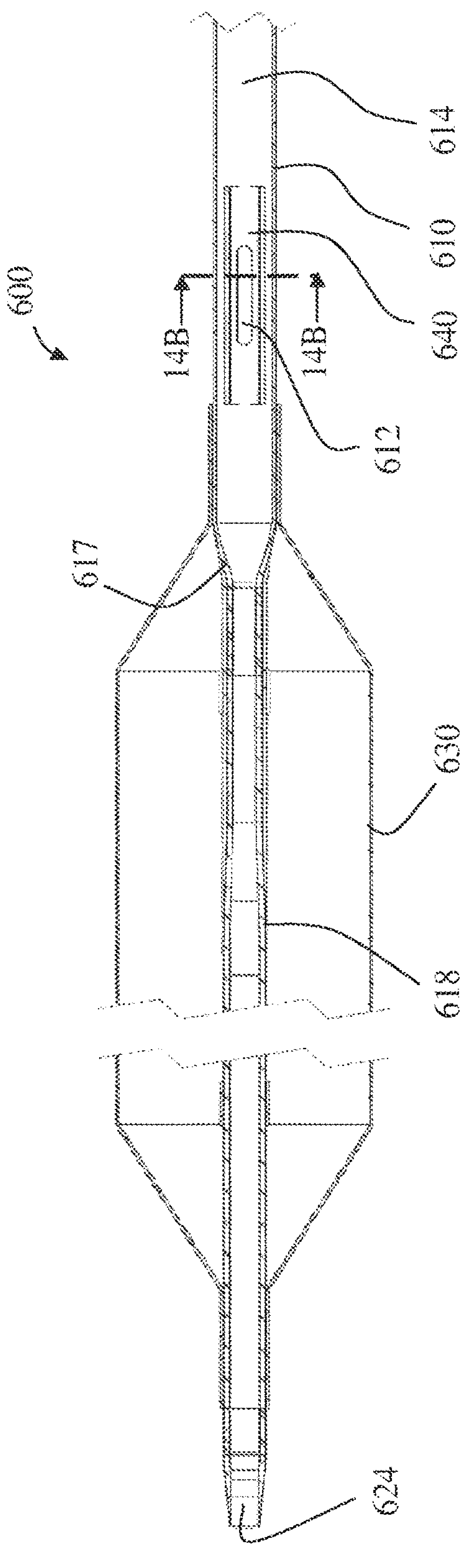

FIG 14A

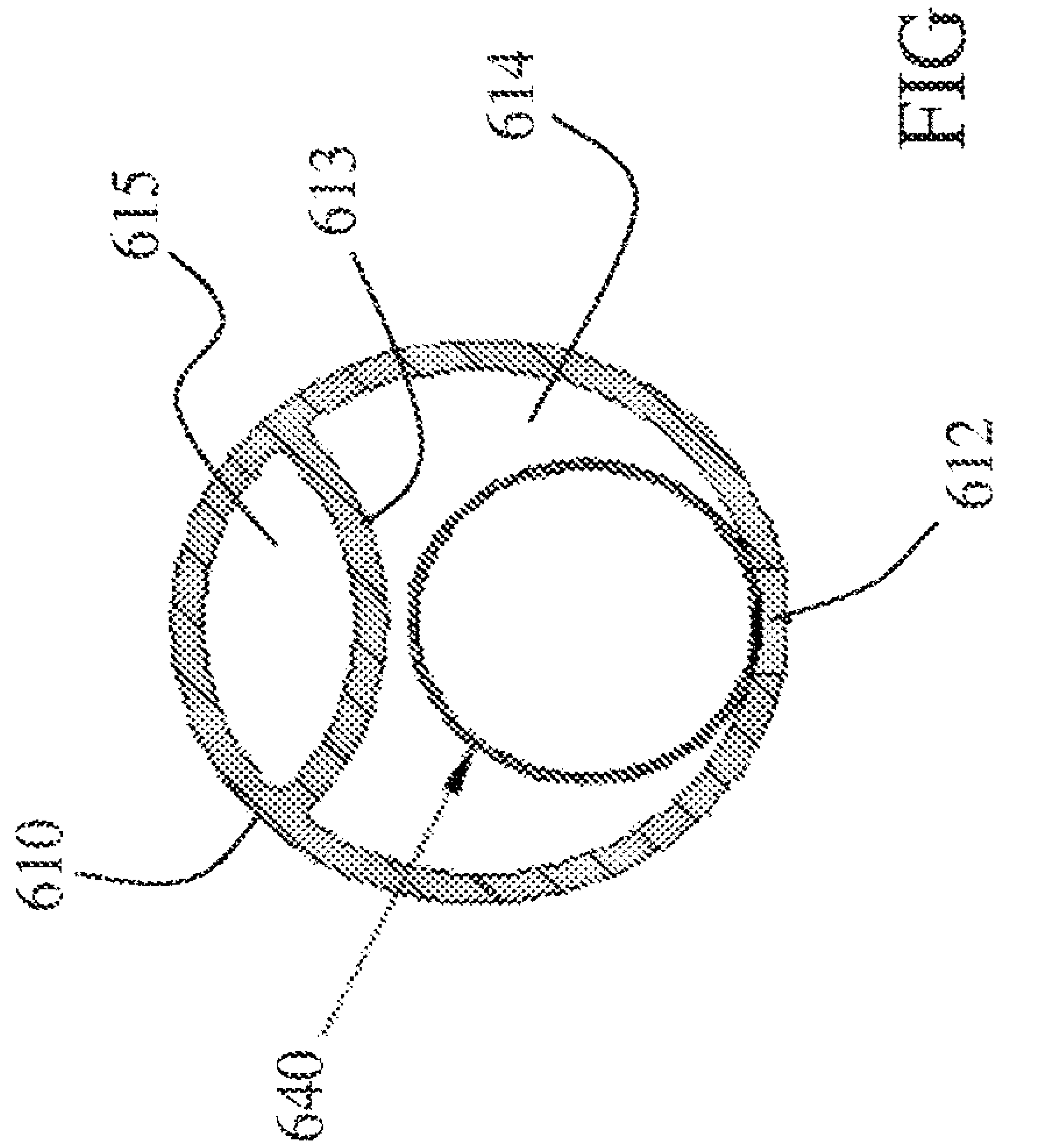

FIG 14B

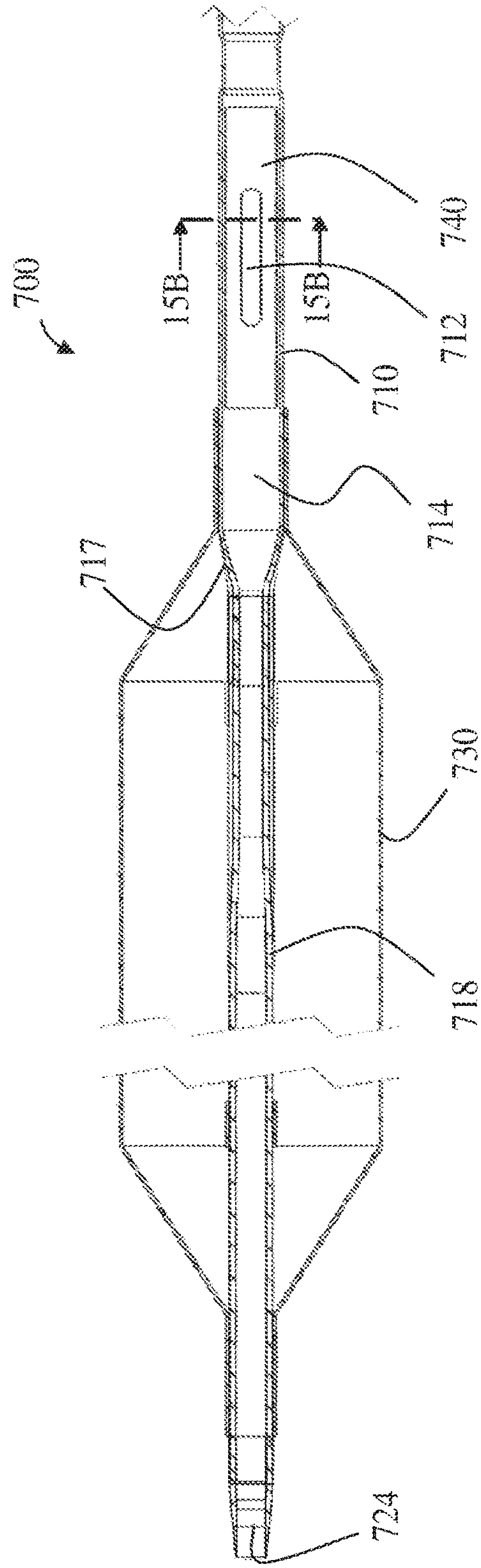

FIG 15A

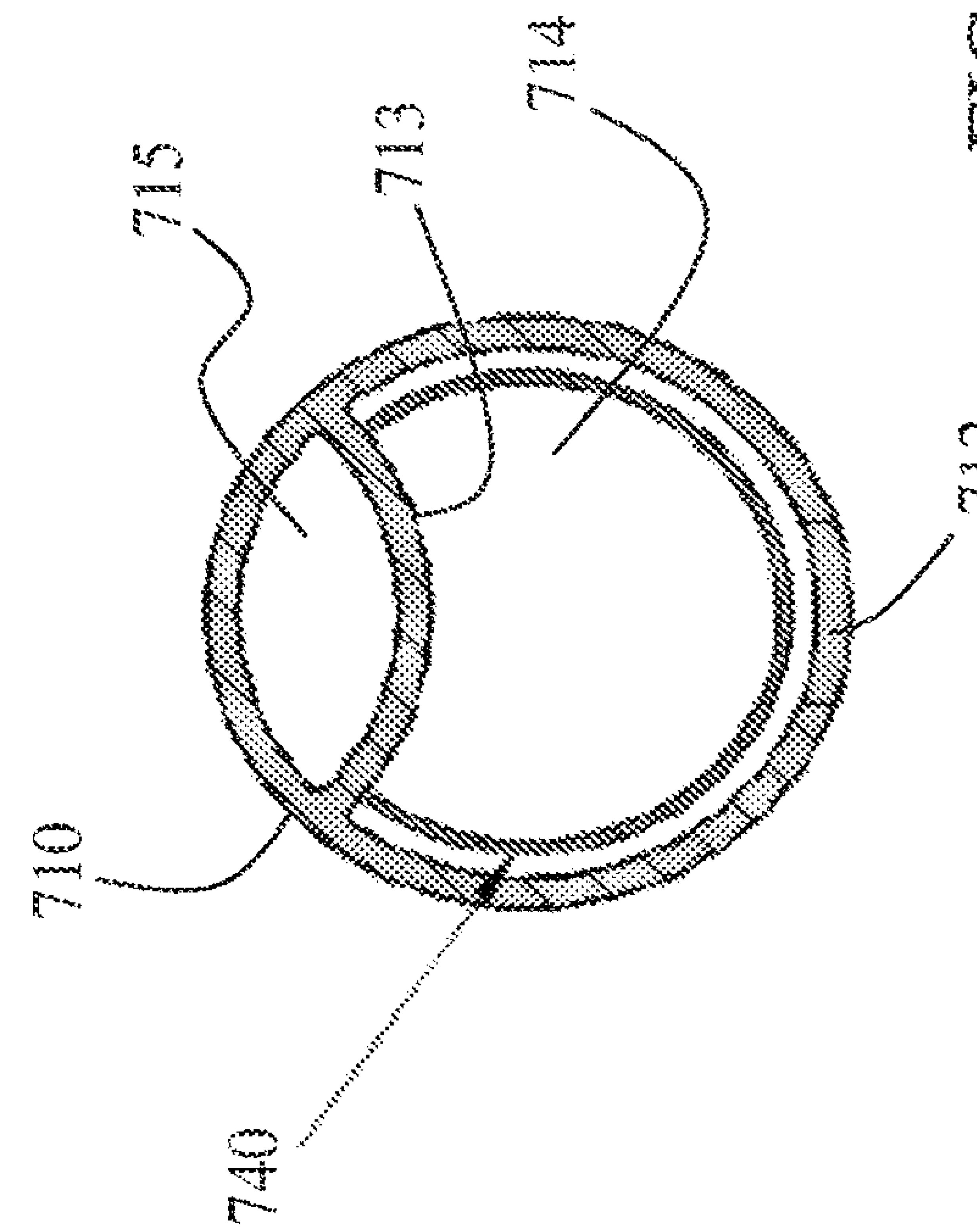

FIG 15B

INFUSION CATHETERS AND RELATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 17/367,838, filed on Jul. 6, 2021, which is a continuation of U.S. patent application Ser. No. 15/430,776, filed on Feb. 13, 2017, now U.S. Pat. No. 11,052,188, which is a continuation of U.S. patent application Ser. No. 14/760,774, filed on Jul. 14, 2015, now U.S. Pat. No. 10,363,358, which is a National Stage Entry of PCT Patent Application No. PCT/US2014/010752 filed on Jan. 8, 2014, which claims the benefit of and priority to U.S. Provisional Patent Application No. 61/752,649, filed on Jan. 15, 2013. The entire contents of each of the foregoing applications are incorporated by reference herein.

BACKGROUND OF THE INVENTION

The present invention, in some embodiments thereof, relates to medical devices, and in particular to balloon catheters applicable for treating blood vessels.

Balloon catheters are well known and used in treating various conditions in blood vessels. Two main types of balloon catheters in that area are dilatation balloon catheter, used to treat narrowed or stenotic portions of the vessel and recover flow (e.g., angioplasty balloon catheters), and occlusion balloon catheters, used to temporarily block flow out of a vessel segment while infusing fluid (e.g., medicament, contrast enhancer or flushing material) therein.

Some balloon catheters have at least three parallel functions, including: balloon inflation, travel over a guide wire, and infusion or dispersion of fluids therethrough. Such balloon catheters often include at least three lumens passing there along, including an inflation lumen, a guidewire lumen and an infusion lumen, correspondingly. In some occasions it is suggested to treat a blood vessel with a balloon catheter comprising an infusion exit opening located proximally to the balloon member, particularly if the balloon member is used for occlusion at least partially during infusion. U.S. Pat. No. 7,182,755 describes a use of an occlusion balloon catheter with a proximal infusion opening for treating hemodialysis vascular access. U.S. Pat. No. 5,368,567 describes a dilatation balloon catheter with a proximal infusion opening. The disclosures of both patents are fully incorporated herein by reference.

In some such occasions, minimization of catheter's lumens cross-sections is advantageous. In one example, there may be a need for a small diameter catheter for intraluminal passage (e.g., 3F to 5F) so it is more complex to introduce three lumens. In a second example, there may be a need to fortify the catheter shaft for high pressure dilatations (as in vascular access recanalization in certain anatomies), so it may be advantageous to decrease overall lumens size in a certain shaft diameter.

SUMMARY OF THE INVENTION

The present disclosure relates to a PTA (percutaneous transluminal angioplasty) balloon catheter, preferably high-pressure type, optionally introducible as an over the wire catheter. The catheter possess the attribute of injecting fluid to the treated site through a dedicated opening proximal to the balloon member, for introduction of fluids such as contrast enhancing material and/or medication. Fluid injection can be performed simultaneously while inflating or deflating the balloon, or while balloon is maintained inflated. Possibly, number of radiopaque markings (preferably two or more) is present to define the working length of the balloon and facilitate in balloon placement. In some embodiments, a single lumen is used, at least in part, both for fluids transfer and dispersion ("infusion") as well as for guide wire passage. In some such embodiments, a valve mechanism is used to sustain selective operability of the lumen so that fluids will disperse mostly or solely through the proximal dispersion opening rather than the guide wire distal exit opening. In one example, the catheter ends with a tip, optionally an atraumatic tip with a check-valve integrated inside the guide wire lumen distal to the injection opening to allow infusion of fluids with or without the guide wire. Such a device can be used for multiple functions in sequence and/or in parallel, such as: performing high-pressure angioplasty in native arteriovenous dialysis fistulae or synthetic grafts; perform balloon dilatation and simultaneous contrast material injection; using smaller amounts of contrast enhancing material; decreasing use of angiograms and radiation exposure to staff and patient.

Catheters according to the present disclosures may be used also for embolectomy and declotting procedures. A device according to the present invention may include, though not necessarily, a relatively soft and compliant balloon fixed at the distal tip. The catheter possess the attribute of injecting fluid to the treated site through a dedicated opening proximal to the balloon for introduction of fluids such as clot dissolving material (such as t-PA). Fluid injection can be performed simultaneously while inflating or deflating the balloon, or while balloon is maintained inflated. Such a device can be used for multiple functions in sequence and/or in parallel, such as: performing balloon occlusion (possibly following dilatation) and simultaneous clot dissolving fluid injection; reducing the risk of clot migration to the arterial side during thrombectomy procedure and injection of contrast to the clogged access; using smaller amounts of contrast enhancing material; decreasing use of angiograms and radiation exposure to staff and patient.

According to an aspect of some embodiments of the present invention there is provided a catheter comprising a shaft, having a length, a proximal end and a distal end, and a wall enclosing an infusion lumen extending along the length and opened at both proximal and distal ends with corresponding proximal opening and distal opening. The infusion lumen is further opened with a lateral infusion opening disposed in the wall between the proximal end and distal end. The catheter also includes an inflatable member connected to the shaft adjacent the distal end and distal to the lateral infusion opening, and an inflation lumen sealed to the infusion lumen, extending between a proximal inflation opening at the proximal end and a distal inflation port opened to an interior of the inflatable member. A valving mechanism is selectively operable to block the distal opening thereby allowing infusion exit mostly or solely through the lateral infusion opening rather than mostly or solely through the distal opening.

A method for operating the catheter includes at least one of the following steps (not necessarily in same order):

1. inserting a guidewire in a luminal vessel;
2. delivering the catheter in the luminal vessel over the guidewire to a chosen target;
3. inflating the inflatable member to occlude the luminal vessel at the target; and

4. infusing a fluid through the lateral infusion opening proximal to the inflatable member such that no fluid passes beyond the inflatable member.

In some embodiments, the infusing occurs while the inflatable member is filled. Optionally, the method comprises a step of deflating the inflatable member after the infusing. Optionally, inflating the balloon generates a dilatation force in a magnitude above a mechanical yield point of a stenotic blood vessel wall.

In an aspect of some embodiments according to the present invention, there is provided a catheter which comprises an infusion wall enclosing an infusion lumen. In some embodiments the infusion lumen extends axially along the infusion wall, and comprises a proximal wall segment, a distal wall segment and an intermediate wall segment extending therebetween. In some embodiments, the proximal wall segment comprises a proximal guidewire opening and the distal wall segment comprises a distal guidewire opening. In some embodiments, the intermediate wall segment adjoins the distal wall segment with a narrowing. In some embodiments, the intermediate wall segment includes a fluid inlet appositional to the proximal wall segment and a fluid outlet appositional to the distal wall segment. In some embodiments, the proximal wall segment adjoins the intermediate wall segment with a widening. The narrowing and/or widening may be gradual.

In some embodiments, the infusion lumen in distal wall segment is sized, shaped, and/or inner surface of the distal wall segment is textured, such, to build a distal pressure gradient allocating a distal flow rate through the distal guidewire opening being 40% or less a fluid outlet flow rate through the fluid outlet, optionally 20% or less, optionally 10% or less, optionally 5% or less, optionally 2% or less. In some embodiments, the infusion lumen in proximal wall segment is sized, shaped, and/or inner surface of the proximal wall segment is textured, such, to build a proximal pressure gradient allocating a negative flow rate through the proximal guidewire opening being 40% or less a fluid outlet flow rate through the fluid outlet, optionally 20% or less, optionally 10% or less, optionally 5% or less, optionally 2% or less.

Optionally, the distal wall segment and/or the proximal wall segment is unobstructed, such as with a wire passing therein. Optionally and alternatively, the distal wall segment and/or the proximal wall segment is obstructed, partially or fully, with a guidewire, optionally a 0.035" guidewire, or optionally with a 0.025" guidewire, or optionally a 0.018" guidewire, or optionally with a 0.014" guidewire, or any other size, higher, lower or of an intermediate size.

In some embodiments, a cross section area of the fluid outlet divided by a cross section area of the distal guidewire opening is at least 1.2, optionally at least 1.5, optionally at least 2, optionally at least 5, optionally at least 10, or higher, or lower, or intermediate. Optionally, the distal wall segment is at least 10 mm in length, optionally at least 20 mm, optionally at least 50 mm, optionally at least 100 mm, or higher, or lower, or intermediate. In some embodiments, the distal pressure gradient is determined according to an infusion fluid viscosity of at least 0.5 centipoises, optionally at least 0.65 centipoises, optionally at least 3 centipoises, optionally at least 8 centipoises, optionally at least 14 centipoises, or higher, or lower, or intermediate.

In some embodiments, a cross section area of the proximal guidewire opening is equal to or less than a cross section area of the distal guidewire opening. In some embodiments, a cross section of the infusion lumen in the distal wall segment and/or in the proximal wall segment is circular and 0.3 to 1.5 mm in diameter, optionally 0.9 to 1 mm in diameter, optionally 0.3 to 0.9 mm in diameter. In some embodiments, a cross section of the infusion lumen in the intermediate wall segment is noncircular shaped with a smallest distance between antipodal points at an inner boundary thereof being at least 0.5 mm. Optionally, a cross section of the infusion lumen in the intermediate wall segment is crescent shaped with a smallest distance between two opposing arcs at an inner boundary thereof being at least 0.5 mm. Optionally, a cross section area of the infusion lumen in the intermediate wall segment is at least 1.5 mm^2, optionally at least 1.75 mm^2, optionally at least 2 mm^2.

In some embodiments, the fluid outlet includes at least one opening such as a hole and/or at least one slit which may be configured to open above a predetermined infusion pressure of at least 1 bar, optionally of at least 2 bars.

In some embodiments, the catheter also includes an inflatable member and an inflation wall enclosing an inflation lumen, with the infusion wall, along a length thereof. The inflatable member may be a dilatation balloon comprising a non-compliant or a semi-compliant material, or, optionally and alternatively, a non-compliant material. In some embodiments, the inflatable member is provided in between the fluid outlet and the distal guidewire opening. Optionally and alternatively, the fluid outlet includes a proximal-most opening and a distal-most opening, wherein the inflatable member extends therebetween.

In some embodiments, a guidewire seal is provided in the infusion lumen between the fluid inlet and the proximal guidewire opening and/or between the fluid outlet and the distal guidewire opening. Optionally, the guidewire seal allows a guidewire travel therethrough. Optionally, the guidewire seal is annular shaped and inflatable to decrease in inner diameter below to a predetermined guidewire diameter. Optionally, alternatively or additionally, a zero seal is provided between the fluid inlet and the proximal guidewire opening and/or between the fluid outlet and the distal guidewire opening. Optionally, the zero seal is normally closed to fluid flow at the absence of a guidewire passing therethrough.

In some embodiments, the fluid outlet includes a single opening with a total opened area being equal to or greater than the cross section area of infusion lumen proximal to the fluid outlet less a cross section area of a guidewire with a minimal prescribed diameter. Optionally, a structural fortification is added to the infusion wall about the opening. Optionally, the fortification includes a mesh patch, a tube insert or a sheet insert.

In one specific implementation, a catheter has an infusion wall enclosing an infusion lumen extending axially there along. The infusion lumen includes three segments: a proximal wall segment, a distal wall segment and an intermediate wall segment extending therebetween. The proximal wall segment comprises a proximal guidewire opening and the distal wall segment comprises a distal guidewire opening so that a guidewire may be positioned within the infusion lumen. The intermediate wall segment adjoins the distal wall segment with a narrowing such that the distal wall segment has a smaller minimal cross sectional area than a minimal cross sectional area of said intermediate wall segment. When a guidewire is positioned in the infusion lumen, it fits tighter in the distal wall segment of the infusion lumen than it does in the larger intermediate wall segment. The narrowed distal wall segment is narrowed for a length of at least 20 mm. This effectively seals the distal end of the catheter, while at the same time allowing fluid to relatively freely migrate from a fluid inlet in the intermediate wall segment, around the guidewire in the intermediate wall segment, and out of a fluid outlet in the intermediate wall segment. In some embodiments, the cross sectional area of the fluid outlet is equal to or greater than the minimal cross sectional area of the intermediate wall segment minus the minimal cross sectional area of the distal wall segment. In some embodiments, a similar at least 20 mm length of narrowed portion of the infusion lumen is positioned on the proximal side of the catheter as well.

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

In the Drawings:

FIGS. **1**A-D schematically illustrate an exemplary balloon catheter comprising a combined infusion-guidewire lumen with selective valving mechanism, in accordance with embodiments of the present invention;

FIGS. **2**A-B schematically illustrate portions in cross section of an exemplary balloon catheter and seals provided therein, in accordance with embodiments of the present invention;

FIGS. **3**A-B schematically illustrate portions in cross section of a different exemplary balloon catheter and seals provided therein, in accordance with embodiments of the present invention;

FIGS. **4**A-B schematically illustrate cross sections in portions of two different exemplary catheters comprising combined infusion-guidewire lumen, in accordance with embodiments of the present invention;

FIGS. **5**A-H schematically illustrate cross sections in portions of different exemplary catheters, in accordance with embodiments of the present invention;

FIGS. **6**A-B schematically illustrate an exemplary infusion lumen comprising a first exemplary valving mechanism, in accordance with embodiments of the present invention;

FIGS. **7**A-B schematically illustrate balloon catheter incorporating exemplary valving mechanisms differentiated by balloon location relative to fluid outlet, in accordance with embodiments of the present invention;

FIGS. **8**A-B schematically illustrate an exemplary infusion lumen comprising an exemplary valving mechanism with an additional exemplary backflow seal, in accordance with embodiments of the present invention;

FIGS. **9**A-B schematically illustrate an exemplary infusion lumen comprising an exemplary valving mechanism with additional exemplary proximal and distal sealing sets, in accordance with embodiments of the present invention;

FIGS. **10**A-I illustrate side views and cross section views of an exemplary angioplasty infusion balloon catheter comprising a guidewire based valving mechanism, in accordance with embodiments of the present invention;

FIGS. **11**A-C schematically illustrate different exemplary cross section shapes for an intermediate section of an infusion lumen, in accordance with embodiments of the present invention;

FIGS. **12**A-C schematically illustrate different exemplary fluid outlet types and/or distribution, in accordance with embodiments of the present invention;

FIGS. **13**A-B schematically illustrate cut views of an exemplary balloon catheter with a single proximal fluid outlet comprising a first exemplary fortification, in accordance with embodiments of the present invention;

FIGS. **14**A-B schematically illustrate cut views of an exemplary balloon catheter with a single proximal fluid outlet comprising a second exemplary fortification, in accordance with embodiments of the present invention; and

FIGS. **15**A-B schematically illustrate cut views of an exemplary balloon catheter with a single proximal fluid outlet comprising a third exemplary fortification, in accordance with embodiments of the present invention.

DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The following preferred embodiments may be described in the context of exemplary balloon catheters for treating blood vessels. However, the invention is not limited to the specifically described devices and methods, and may be adapted to various clinical applications without departing from the overall scope of the invention.

Referring to the drawings, FIGS. **1**A-D schematically illustrate an exemplary balloon catheter **1000** comprising a combined infusion-guidewire lumen (referred to as infusion lumen **1114**) with selective valving mechanism **1300**. Catheter **1000** includes a shaft **1100** having a length, a proximal end **1001** and a distal end **1002**, and a wall enclosing infusion lumen **1114** which is extending along shaft's **1100** length and opened at both proximal end **1001** and distal end **1002** with corresponding proximal opening **1112** and distal opening **1118**. Infusion lumen **1114** is further opened with a lateral infusion opening **1116** (or optionally a number of openings) disposed in shaft's **1100** wall between proximal end **1001** and distal end **1002**.

An inflatable member **1200** is connected to shaft **1100** adjacent its distal end, distal to lateral infusion opening **1116**. An inflation lumen **1124**, sealed to infusion lumen **1114**, extends between a proximal inflation opening **1122**, at shaft's **1100** proximal end, and a distal inflation port **1126**, opened to an interior of inflatable member **1200**. Inflatable member **1200** may be a compliant balloon, a semi-compliant balloon or a non-compliant balloon.

A valving mechanism according to the present disclosure may be any type of controller, such as a mechanical device, for selectively controlling a flow parameter of a fluid, for example a flow rate. A valving mechanism may be set between two or more modes that inhibit fluid flow by different amounts. In some cases, the modes may include a fully closed mode in which flow is substantially absent, and a fully opened valve in which fluid is allowed to travel substantially unhindered by the valving mechanism. Intermediate flow restrictions are also possible. According to some preferred embodiments of the present disclosure, a valving mechanism includes an elongated member such as a wire (e.g., a guide wire) operational to selectively pass through or withdraw from an infusion lumen portion sized and shaped substantially the same as external boundaries of a correlating portion thereof, being substantially narrowed as compared to a proximal portion of the infusion lumen located between a fluid inlet and a fluid outlet, such that when the wire occupies the narrowed infusion lumen portion then no flow or at least substantially no flow will pass therethrough. When the obstructing wire is fully withdrawn from the constricted or narrowed infusion lumen portion, fluid can pass therethrough. In an optional alternative embodiment, other valving means may be applied so that no fluid may pass through the narrowed infusion lumen portion also when the obstructing wire is absent, so that all or at least substantially all fluid will be delivered through a fluid outlet that is positioned proximal to the narrowed infusion lumen portion.

As shown in FIGS. **1**, guidewire-based valving mechanism **1300** may be provided in infusion lumen **1114** distal to lateral infusion opening **1116**. Valving mechanism **1300** is selectively operable to block distal opening **1118** of infusion lumen **1114** such that fluid passing distally through infusion lumen **1114** shall exit mainly or solely through lateral infusion opening **1116** rather than through distal opening **1118**. In case that valving mechanism **1300** is set not to block distal opening **1118**, flow may pass via distal opening **1118** at all or in a greater rate.

As shown, infusion lumen **1114** defines a first segment **1320**, extending between proximal opening **1112** and a boundary **1340** (shown adjacent to lateral infusion opening **1116** although it may be further distal), and a second segment **1330**, extending between boundary **1340** and distal opening **1118**. In some embodiments, in first segment **1320**, infusion lumen **1114** has a first minimal cross section area, and in second segment **1330**, infusion lumen **1114** has a second minimal cross section area smaller than the first minimal cross section than in first segment **1320**. Valving mechanism **1300** includes an elongated member, preferably a guide wire **1310** selectively disposable in infusion lumen **1114** at first segment **1320** and/or second segment **1330**. Guide wire **1310** is sized and configured to pass through proximal opening **1112**, infusion lumen **1114** and/or distal opening **1118**, and therefore allow an over-the-wire delivery of catheter **1000** thereupon. Optionally and alternatively, catheter **1000** is configures for rapid exchange deliveries.

In some embodiments, the second minimal cross section is sized and shaped such that guide wire **1310** can be selectively fit, snugly, in the second minimal cross section in order to achieve blocking of distal opening **1118** and/or second segment **1330** distal to lateral infusion opening **1116**. In some embodiments, the second minimal cross section is circular whereas the first minimal cross section is sized and shaped to virtually enclose a circle with identical dimensions to said second minimal cross section (as shown in the shape difference of infusion lumen **1114** in FIG. 1B vs. FIG. **1**C). The first minimal cross section may be of any shape such as circular, elliptic or crescent. FIGS. **4**A-B schematically illustrate cross sections of two other possible exemplary catheter portions **1000'** and **1000"** which comprise combined infusion-guidewire lumens **1114'** and **1114"**, respectively. Both catheters **1000'** and **1000"** are over-the-wire type balloon catheters. In FIG. **4**A, an inner wall **1125'** dividing between infusion lumen **1114'** and inflation lumen **1124'** is partially curved to allow partial nesting with part of a guide wire **1310'** periphery in contact. Other part of guide wire periphery not in contact with inner wall **1125'** is opened at least partially to infusion lumen **1114'** interior so that fluid passing in the lumen may contact it. FIG. **4**B shows infusion lumen **1114"** and inflation lumen **1124"** divided with a straight inner wall **1125"**, while guide wire **1310"** is mostly opened to infusion lumen **1114"** interior and may be only tangential to inner wall **1125"**.

In an aspect of some embodiments, a method is disclosed for operating a balloon catheter, such as balloon catheter **1000**, according to the present disclosure, comprising at least one of the following steps (not necessarily in same order):

1. inserting guidewire **1310** in a luminal vessel, such as a vein or an artery, optionally a coronary, a peripheral or dialysis target vessel;
2. delivering balloon catheter **1000** in the luminal vessel over guidewire **1310** to a chosen target;
3. inflating inflatable member **1200** to occlude, at least partially, the luminal vessel at the target;
4. infusing a fluid (e.g., a liquid or suspended medicament or contrast enhancing medium) through lateral infusion opening **1116** such that minimal or no fluid passes beyond inflatable member **1200**.

In some embodiments, steps **3** and **4** are performed simultaneously and/or in overlap. In some embodiments, guide wire **1310** is selectively occupying or withdrawn from second segment **1330** in infusion lumen **1114** according to need. In some embodiments, catheter **1000** first engages guide wire **1310** by inserting it via distal opening **1118**, or alternatively, by inserting guide wire **1310** in infusion lumen **1114** via proximal opening **1112**. In some embodiments, the infusing occurs while the inflatable member is filled and/or expanded, optionally fully or partially. Optionally, the inflatable member is deflated after the infusing. In some embodiments, the inflating generates a dilatation force in a magnitude above a mechanical yield point of a stenotic blood vessel wall. Optionally, alternatively or additionally, the mechanical interaction between the filled and/or expanded inflatable member with the blood vessel portion in contact creates a sealing thus obstructing and/or diminishing substantially a fluid passing therebetween.

In different exemplary embodiments, a valving mechanism may include an additional valve or a seal for sealing around a guide wire passing therethrough, and/or selectively seal an opening or a segment of an infusion lumen when the guide wire is removed or otherwise absent. In some embodiments, a catheter includes at least one one-way valve allowing a guide wire passing therethrough while sealing fluid passage. Optionally, the one-way valve is disposed adjacent to catheter's distal end and/or between a distal opening and a lateral infusion opening in the infusion lumen. Optionally, alternatively or additionally, the one-way valve is disposed adjacent to catheter's proximal end and/or between a proximal opening and a lateral infusion opening in the infusion lumen. Optionally, the catheter and/or the valving mechanism includes a septum seal.

FIGS. **2**A-B schematically illustrate portions in cross section of an exemplary balloon catheter **2000** and seals provided therein. Optionally and alternatively, only one seal of FIG. **2**A or FIG. **2**B is provided therein. FIG. **2**A shows a proximal portion of balloon catheter **2000**, comprising a wall **2100** enclosing an infusion lumen **2114** openable at proximal infusion inlet or port **2112** to an infusion fluid source (not shown), as well as an inflation lumen (not shown) openable to proximal inflation port **2122**. As shown, a guide wire **2310** is passable through infusion lumen **2114** and proximal infusion port **2112** and therefore a proximal valving mechanism **2400** is required to avoid backflow via proximal infusion port **2112**. In some embodiments, proximal valving mechanism **2400** includes a proximal seal **2410** in the form of a "wire seal" adapted to maintain sealing around periphery of guide wire **2310**, if present as shown. As such, proximal seal **2410** may include a plurality of overlapping seal segments adapted to extend or narrow against outer periphery of the guide wire while maintaining sealing. In some embodiments, proximal valving mechanism **2400** may also include a zero seal (which is "normally sealing"), in addition to the wire seal, not shown, adapted to seal fluid backflow through proximal infusion valve port **2112** when a wire is absent.

FIG. **2**B shows a distal portion of balloon catheter **2000** in which an inflatable member (balloon **2200**) is fixated thereto. Infusion lumen **2114** is opened to outer environment with a lateral infusion opening **2116**. Distally to lateral infusion opening **2116** in infusion lumen **2114** there is provided a proximal valving mechanism **2300** comprising a septum seal **2320**, optionally made of a highly elastic and/or a viscoelastic material, allowing distal sealing either if guide wire **2310** is absent (not shown) or passes therethrough (as shown).

FIGS. **3**A-B schematically illustrate portions in cross section of a different exemplary balloon catheter **3000** and optional exemplary seals provided therein. Balloon catheter **3000** includes a wall **3100** enclosing an infusion lumen **3114** openable at a proximal infusion inlet port **3112** to an infusion fluid source (not shown), as well as an inflation lumen (not shown) openable to proximal inflation port **3122**. An inflatable member (balloon **3200**) is fixated at distal portion of catheter **3000**. As shown, guide wire **3310** is passable through infusion lumen **3114** however it does not pass through proximal infusion port **3112** but rather through a dedicated guide wire port **3130**. Therefore a proximal valving mechanism **3400** comprising an O-ring or a septum seal **3410**, is used in guide wire port **3130** in order to avoid backflow of infusion fluid therethrough. In the distal portion of balloon catheter **3000**, as shown in FIG. **3**B, infusion lumen **3114** is shown opened to outer environment with a lateral infusion outlet or opening **3116**. Distally to lateral infusion opening **3116** in infusion lumen **3114** there is provided a distal valving mechanism **3300** comprising a normally closed seal **3320** adapted to maintain sealing therethrough to infusion fluids either if guide wire **3310** passes therethrough or is absent. In some embodiment, seal **3320** is an inflatable doughnut shaped, optionally continuously pressurized, so that it maintains a minimal sized core opening changeable from zero (when guide wire **3310** is absent) to outer diameter of guidewire **3310** if it passes therethrough.

In some embodiments, balloon catheter **3000** ends distally with a soft, elastic and/or pliable descending conic member **3118** which is normally tapered with a distal inner diameter substantially smaller than its proximal inner diameter at least at non-stressed and/or non-stretched form. If stretched out, for example in case a guide wire passes therethrough and having dimensions greater than those imposed by the non-stretched conic member **3118**, it maintains a sealed distal end around outer boundaries of conic member **3118**. Such sealing function may achieve at least one of: blocking fluid therethrough from infusion lumen to our environment of any infusion fluid such as saline or medicament, and/or blocking fluid travel therethrough from outer environment and into infusion lumen of body fluid such as blood. In some embodiments, conic member **3118** is designed, sized and/or configured such that guide wires having outer diameters between 0.01- to 0.2", optionally 0.018" to 0.035" or higher or lower or intermediate, are unhinderly passable therethrough, and optionally also stretching it at least partially to a radially extended form. In some embodiments, conic member **3118** is normally sealed so that in absence of any wire extending therethrough it is fully compressed and sealed to fluids, at least at its distal-most portion.

Reference is made to FIGS. **5**A-H which schematically illustrate cross sections in portions of different exemplary catheters, in accordance with embodiments of the present invention. All these cross sections represent portions of corresponding infusion lumens, each extending between a distal fluid inlet and a proximal fluid outlet. FIG. **5**A shows a portion **3510** having a circular cross section with a wall **3511** enclosing a first infusion lumen **3512** with a dedicated area **3513** for partial nesting of a guidewire (not shown) shaped to enclose most of guidewire's periphery, and a second inflation lumen **3514**. Optionally, portion **3510** is of a 5.5 French (F) PTA catheter whereas infusion lumen **3512** area is about 1.2 mm^2 and inflation lumen **3514** area is about 0.34 mm^2. FIG. **5**B shows a portion **3520** having a circular cross section with a wall **3521** enclosing a first infusion lumen **3522** with a dedicated area **3523** for partial nesting of a guidewire (not shown) shaped to enclose approximately half of guidewire's periphery, and a second inflation lumen **3524**. Optionally, portion **3520** is of a 5.5F PTA catheter whereas infusion lumen **3522** area is about 1.28 mm^2 and inflation lumen **3524** area is about 0.31 mm^2. FIG. **5**C shows a portion **3530** having a circular cross section with a wall **3531** enclosing a first infusion lumen **3532** with a dedicated area **3533** for partial nesting of a guidewire (not shown) shaped to enclose most of guidewire's periphery, and a second inflation lumen **3534**. Optionally, portion **3530** is of a 5F occlusion balloon catheter whereas infusion lumen **3532** area is about 0.82 mm^2 and inflation lumen **3514** area is about 0.54 mm^2. FIG. **5**D shows a portion **3540** having a circular cross section with a wall **3541** enclosing a first infusion lumen **3542** with a dedicated area **3543** for partial nesting of a guidewire (not shown) shaped to enclose approximately half of guidewire's periphery, and a second inflation lumen **3544**. Optionally, portion **3540** is of a 6F PTA catheter whereas infusion lumen **3542** area is about 1.52 mm^2 and inflation lumen **3444** area is about 0.5 mm^2. FIG. **5**E shows a portion **3550** having a circular cross section with a wall **3551** enclosing a first infusion lumen **3552** with a dedicated area **3553** for partial nesting of a guidewire (not shown) shaped to enclose most of guidewire's periphery, and a second inflation lumen **3554**. Optionally, portion **3550** is of a 5F occlusion balloon catheter whereas infusion lumen **3552** area is about 1.09 mm^2 and inflation lumen **3554** area is about 0.27 mm^2. FIG. **5**F shows a portion **3560** having a circular cross section with a wall **3561** enclosing a first infusion lumen **3562** with a dedicated area **3563** for partial nesting of a guidewire (not shown) shaped to enclose most of guidewire's periphery, and a second inflation lumen **3564**. Optionally, portion **3560** is of a 6F PTA catheter whereas infusion lumen **3562** area is about 1.48 mm^2 and inflation lumen **3564** area is about 0.69 mm^2. FIG. **5**G shows a portion **3570** having a circular cross section with a wall **3571** enclosing a first infusion lumen **3572**, a second guidewire lumen **3573** and a third inflation lumen **3574**. Optionally, portion **3570** is of a 5.5F PTA catheter whereas infusion lumen **3572** area is about 0.49 mm^2, guidewire lumen **3573** area is about 0.69 mm^2 and inflation lumen **3574** area is about 0.35 mm^2. FIG. **5**H shows a portion **3580** having a circular cross section with a wall **3581** enclosing a first infusion lumen **3582** with enough space yet without a dedicated area for partial nesting of a guidewire (not shown), and a second inflation lumen **3583**. Optionally, portion **3580** is of a 5.5F PTA catheter whereas infusion lumen **3582** area is about 1.49 mm^2 and inflation lumen **3583** area is about 0.27 mm^2.

Reference is now made to FIGS. **6**A-B which schematically illustrate an exemplary infusion lumen **110**IL, as part of a catheter, comprising a first exemplary valving mechanism, in accordance with embodiments of the present invention. The catheter includes an infusion wall **110** enclosing infusion lumen **110**IL that extends axially therealong. Infusion wall includes a proximal wall segment **115**, a distal wall segment **113** and an intermediate wall segment **111** extending therebetween. Proximal wall segment **115** comprises a proximal guidewire opening **118** and distal wall segment **113** comprises a distal guidewire opening **119**. A guidewire **120** is shown extending through infusion lumen **110**IL having its distal part provided through distal guidewire opening **119** and its proximal part provided through proximal guidewire opening **118**. During treatment, including catheter delivery, deployment or withdrawal, guidewire **120** may pass into infusion lumen **110**IL through proximal guidewire opening **118** or through distal guidewire opening **119**.

Proximal wall segment **115** adjoins intermediate wall segment **111** with a widening **114**, and intermediate wall segment **111** adjoins distal wall segment **113** with a narrowing **112**. Widening **114** and/or narrowing **112** may be gradual or steep.

Intermediate wall segment **111** includes a fluid inlet **116** appositional to proximal wall segment **115** and a fluid outlet **117** appositional to distal wall segment **113**.

Infusion lumen **110**IL is shown during fluid dispersion when fluid inlet **116** is located outside a patient body and fluid outlet **117** is located inside the patient body in a specific location in a bodily lumen, optionally a blood vessel such as a vein or an artery, optionally in apposition to a lesion or a stenosis. A fluid inlet flow rate Fin travels in infusion lumen **110**IL through fluid inlet **116** while a fluid outlet flow **116** while a fluid outlet flow rate Fout **1** travels out of infusion lumen **110**IL to a target location inside patient's body through fluid outlet **117**.

In some embodiments, infusion lumen **110**IL in distal wall segment **113** is sized, shaped, and/or inner surface of distal wall segment **113** is textured, such, to build a distal pressure gradient allocating a distal flow rate Fout**3** through distal guidewire opening **119**, being 40% or less fluid outlet flow rate Fout**1** through fluid outlet **117**, optionally 20% or less, optionally 10% or less, optionally 5% or less, optionally, 2% or less, or higher, or lower, optionally null, or an intermediate percentage; optionally when distal wall segment **113** is unobstructed, such as with guidewire **120**, or optionally when distal wall segment **113** is obstructed with guidewire **120**.

In some embodiments, infusion lumen **110**IL in proximal wall segment **115** is sized, shaped, and/or inner surface of proximal wall segment **115** is textured, such, to build a distal pressure gradient allocating a negative flow rate Fout through proximal guidewire opening **118**, being 40% or less fluid outlet flow rate Fout **1** through fluid outlet **117**, optionally 20% or less, optionally 10% or less, optionally 5% or less, optionally, 2% or less, or higher, or lower, optionally null, or an intermediate percentage; optionally when proximal wall segment **115** is unobstructed, such as with guidewire **120**, or optionally when proximal wall segment **115** is obstructed with guidewire **120**.

Optionally, guidewire **120** is a 0.035" guidewire, or a 0.025" guidewire, or a 0.018" guidewire, or a 0.014" guidewire, or lower, or higher, or intermediate in size.

Distal pressure gradient and/or proximal pressure gradient is optionally determined according to an infusion fluid viscosity of at least 0.65 centipoises ("cP"), or optionally of at least 3 cP, or optionally at least 6 cP, or optionally at least 8 cP; considering that water viscosity at a temperature of 37° C. is approximately 0.69 cP, blood viscosity at same temperature is approximately 3 to 4 cP, and iodine based contrast media is commonly between approximately 4 cP to approximately 12 cP.

In some embodiments, a cross section area of fluid outlet **117** Dprx divided by a cross section area A of distal guidewire opening **119** is at least 1.5, optionally at least 2, optionally at least 3, optionally at least 5, optionally at least 10, or higher, or lower, or an intermediate value. Optionally, a cross section area Dgw of proximal guidewire opening **118** is equal to or less than cross section area A distal guidewire opening **119**.

Optionally, a cross section of infusion lumen **110**IL in distal wall segment **113** and/or in proximal wall segment **115** is circular and 0.3 mm to 1.5 mm in diameter.

In some embodiments, proximal wall segment **115** and/or distal wall segment **113** is at least 10 mm in length, optionally at least 20 mm, optionally at least 50 mm, optionally at least 100 mm, or higher, or lower, or has an intermediate value.

In some embodiments, distal guidewire opening **119** and/or proximal guidewire opening **118** is 0.3 mm to 2 mm in diameter, optionally 0.5 mm to 1.5 mm, optionally 0.9 to 1 mm, or optionally 0.3 mm to 0.9 mm, or optionally about 0.95 mm.

Infusion lumen **110**IL at intermediate wall segment **111** may take any of a plurality of cross sections forms, as long as they are sized and shaped to virtually enclose a circle with dimensions equal or higher than to outer dimensions of guidewire **120** or a thicker guidewire that can be used with the catheter. FIGS. **11**A-C schematically illustrate different exemplary cross section shapes for of infusion lumen **110**IL at intermediate wall segment **111**, in accordance with embodiments of the present invention. FIG. **11**A shows a circular cross section of intermediate wall segment **111** with internal diameter ID equal or greater than guidewire **120** diameter. FIG. **11**B shows a cross section of infusion lumen **110**IL at intermediate wall segment **111** being noncircular shaped with a smallest distance APL between antipodal points AP**1** and AP**2** at an inner boundary thereof. FIG. **11**C shows a cross section of infusion lumen **110**IL at intermediate wall segment **111** being crescent shaped with a smallest distance ARL between two opposing arcs AR**1** and AR**2** at an inner boundary thereof. Optionally distance APL and/or ARL is at least 0.3 mm, optionally at least 0.5 mm, optionally at least 0.9 mm, optionally at least 1.5 mm, optionally at least 3 mm, or higher, or lower, or an intermediate value. In some embodiments, the cross section area of infusion lumen **110**IL at intermediate wall segment **111**, regardless of any chosen shape (as in FIGS. **11**A-C or otherwise) is at least 1 mm^2, optionally 1.5 mm^2, optionally at least 1.75 mm^2, optionally at least 2 mm^2, optionally at least 4 mm^2, or higher, or lower, or of any intermediate value.

Fluid outlet **117** may include any number of openings of any form and size, and of any arrangement with any pattern. As such, fluid outlet may include at least one hole (i.e. a through opening), at least one slit and/or at least one pressure sensitive opening. Optionally the at least one slit is configured to open above a predetermined infusion pressure, optionally of at least 1 bar, optionally at least 2 bar, optionally at least 4 bar, or higher, or lower, or intermediate. Optionally, there are at least 2 openings, optionally at least

4 openings, optionally at least 10 openings, optionally at least 50 openings, or higher, or lower, or an intermediate number. In some embodiments, the overall area of fluid outlet **117** is equal or higher than cross section area (minimal or average, in case it is not constant) of infusion lumen **110**IL at intermediate wall segment **111**, optionally equal or higher than 1.5 times its size, optionally equal or higher than 2 times its size, optionally equal or higher than 5 times its size, or higher, or lower, or an intermediate value. Optionally and alternatively, the overall area of fluid outlet **117** is equal or higher than cross section area of infusion lumen **110**IL at intermediate wall segment **111** less cross section area of guidewire **120**. In some embodiments, fluid outlet **117** may include a number of openings, optionally provided in form of series, optionally around a periphery of the catheter and/or along a portion of its length. At least one opening may be directly opposing an at least one opening at an opposing wall portion of the catheter, and/or at least one opening may be peripherally and/or longitudinally offset to another at least one opening at a different wall portion of the catheter. FIGS. **12**A-C schematically illustrate different exemplary fluid outlet types and/or distribution, in accordance with embodiments of the present invention. FIG. **12**A shows infusion lumen **110**IL at intermediate wall segment **111** with a crescent cross section and a single hole as fluid outlet **117**. FIG. **12**B shows infusion lumen **110**IL at intermediate wall segment **111** with a crescent cross section and a number of holes as fluid outlet **117**. FIG. **12**C shows infusion lumen **110**IL at intermediate wall segment **111** with a crescent cross section and a single pressure sensitive slit as fluid outlet **117**.

In some embodiments the catheter also comprises an inflatable member and an inflation wall enclosing an inflation lumen with the infusion wall along a length thereof. The inflatable member may be a dilatation balloon comprising a non-compliant or a semi-compliant material, or it may be an occlusion balloon comprising a compliant material. FIGS. **7**A-B schematically illustrate balloon catheter incorporating exemplary valving mechanisms differentiated by balloon location relative to fluid outlet, in accordance with embodiments of the present invention. FIG. **7**A shows a catheter **100** which includes infusion wall **110** enclosing infusion lumen **110**IL, similar to as described above. Catheter **100** also includes an inflatable member **136** and an inflation wall **130** enclosing an inflation lumen **1301**L with infusion wall **110** along part of inflation lumen length. Inflation lumen **1301**L includes an inflation inlet **132**, optionally located in relative opposition to proximal guidewire opening **118** and/or to fluid inlet **116**, as well as an inflation outlet **134** located within the sealed inner boundary of inflatable member **136**. Inflatable member may be configured as a dilatation and/or occlusion balloon. As shown, in this example, dilatation member **136** is provided in between fluid outlet **117** and distal guidewire opening **119**. This will allow dispersion of fluid such as contrast enhancing media, flushing fluid, di s solvent and/or medicament only proximal and optionally adjacent to inflatable member **136**.

FIG. **7**B shows a catheter **140** which includes infusion wall **110** enclosing infusion lumen **110**IL, similar to as described above. Catheter **140** also includes an inflatable member **136** and an inflation wall **130** enclosing an inflation lumen **130**IL with infusion wall **110** along part of inflation lumen length. Inflation lumen **1301**L includes an inflation inlet **132**, optionally located in relative opposition to proximal guidewire opening **118** and/or to fluid inlet **116**, as well as an inflation outlet **134** located within the sealed inner boundary of inflatable member **136**. Inflatable member may be configured as a dilatation and/or occlusion balloon. As shown, in this example, fluid outlet **117** includes a proximal-most opening **142** and a distal-most opening **144**, wherein inflatable member **136** extends therebetween. This will allow dispersion of fluid such as contrast enhancing media, flushing fluid, dissolvent and/or medicament proximally and distally, and optionally adjacent, to inflatable member **136**.

In some embodiments other valving or sealing means are provided in addition to the guidewire based valving mechanism in order to improve and/or offer different possibilities for delivering fluids into a target bodily lumen. FIGS. **8**A-B schematically illustrate an exemplary infusion lumen **210**IL, as part of a catheter, comprising an exemplary valving mechanism with additional backflow seal, in accordance with embodiments of the present invention. The catheter includes an infusion wall **210** enclosing infusion lumen **210**IL that extends axially therealong. Infusion wall includes a proximal wall segment **215**, a distal wall segment **213** and an intermediate wall segment **211** extending therebetween. Proximal wall segment **215** comprises a proximal guidewire opening **218** and distal wall segment **213** comprises a distal guidewire opening **219**. A guidewire **220** is shown extending through infusion lumen **210**IL having its distal part provided through distal guidewire opening **219** and its proximal part provided through proximal guidewire opening **218**. During treatment, including catheter delivery, deployment or withdrawal, guidewire **220** may pass into infusion lumen **2101**L through proximal guidewire opening **218** or through distal guidewire opening **219**.

Proximal wall segment **215** adjoins intermediate wall segment **211** with a widening **214**, and intermediate wall segment **211** adjoins distal wall segment **213** with a narrowing **212**. Widening **214** and/or narrowing **212** may be gradual or steep.

Intermediate wall segment **211** includes a fluid inlet **216** appositional to proximal wall segment **215** and a fluid outlet **217** appositional to distal wall segment **213**.

As shown, a guidewire seal **230** is provided in infusion lumen **210**IL between fluid inlet **216** and proximal guidewire opening **218**. In some embodiments, guidewire seal **230** is an inflatable annular seal which includes an annular inflatable body **231** having a lumen **232**, and a seal inlet **234**. In some embodiments, inflatable body **231** has an outer periphery, fixed to infusion wall **210**, and an inner periphery surrounding lumen **232** with a selectively changeable inner diameter. In some embodiments, seal inlet **234** is provided adjacent and in direct fluid communication with fluid inlet **216**, optionally dividing an intake passage at fluid inlet **216** to seal inlet **234** and to an infusion inlet **233**, so that when fluid is forced through fluid inlet **216** it will be divided between filling infusion lumen **210**IL and fluid delivery through fluid outlet **217**, and inflating guidewire seal **230** such that its lumen **232** decreases in diameter down to a minimal degree. In some embodiments, guidewire seal **230** may decrease in inner diameter below to a predetermined guidewire diameter. When guidewire seal **230** is deflated its lumen **232** is relatively enlarged so that guidewire **220** can travel freely therethrough (as shown in FIG. **8**A) whereas when it is inflated to a certain degree, optionally up to a maximal inflation volume, lumen **232** decreases in diameter to equal or less than guidewire **220** outer boundaries (as shown in FIG. **8**B) therefore sealing a fluid passage therebetween. In some embodiments, inflatable body **231** includes a compliant material capable of conforming to guidewire boundaries at certain inner pressures.

FIGS. **9**A-B schematically illustrate an exemplary infusion lumen **310**IL, as part of a catheter, comprising an exemplary valving mechanism with additional exemplary proximal and distal sealing sets, in accordance with embodiments of the present invention. The catheter includes an infusion wall **310** enclosing infusion lumen **310**IL that extends axially therealong. Infusion wall includes a proximal wall segment **315**, a distal wall segment **313** and an intermediate wall segment **311** extending therebetween. Proximal wall segment **315** comprises a proximal guidewire opening **318** and distal wall segment **313** comprises a distal guidewire opening **319**. A guidewire **320** is shown extending through infusion lumen **310**IL having its distal part provided through distal guidewire opening **319** and its proximal part provided through proximal guidewire opening **318**. During treatment, including catheter delivery, deployment or withdrawal, guidewire **320** may pass into infusion lumen **310**IL through proximal guidewire opening **318** or through distal guidewire opening **319**.

Proximal wall segment **315** adjoins intermediate wall segment **311** with a widening **314**, and intermediate wall segment **311** adjoins distal wall segment **213** with a narrowing **312**. Widening **314** and/or narrowing **312** may be gradual or steep.

Intermediate wall segment **311** includes a fluid inlet **316** appositional to proximal wall segment **315** and a fluid outlet **317** appositional to distal wall segment **313**.

As shown, a proximal guidewire seal **330** is provided in infusion lumen **310**IL between fluid inlet **316** and proximal guidewire opening **318**. In some embodiments, proximal guidewire seal **330** is an inflatable annular seal which includes an annular inflatable body **331** having a lumen **332**, and a seal inlet **334**. In some embodiments, inflatable body **331** has an outer periphery, fixed to infusion wall **310**, and an inner periphery surrounding lumen **332** with a selectively changeable inner diameter. In some embodiments, seal inlet **334** is provided adjacent and in direct fluid communication with fluid inlet **316**, optionally dividing an intake passage at fluid inlet **316** to seal inlet **334** and to an infusion inlet **333**, so that when fluid is forced through fluid inlet **316** it will be divided between filling infusion lumen **310**IL and fluid delivery through fluid outlet **317**, and inflating proximal guidewire seal **330** such that its lumen **332** decreases in diameter down to a minimal degree.

A distal guidewire seal **340** is also provided in infusion lumen **310**IL between fluid outlet **317** and distal guidewire opening **319**. In some embodiments, distal guidewire seal **340** is an inflatable annular seal which includes an annular inflatable body **341** having a lumen **342**, and a seal inlet **344**. In some embodiments, inflatable body **341** has an outer periphery, fixed to infusion wall **310**, and an inner periphery surrounding lumen **342** with a selectively changeable inner diameter. In some embodiments, seal inlet **334** is provided in infusion lumen **310**IL so that when pressure arises therein, fluid is forced through fluid outlet **317** in parallel or after to inflating distal guidewire seal **340** such that its lumen **342** decreases in diameter down to a minimal degree.

Tn some embodiments, proximal guidewire seal **330** and distal guidewire seal **340** may decrease in inner diameter below to a predetermined guidewire diameter. When guidewire seals **330** and **340** deflates, their lumens **332** and **342**, respectively, are relatively enlarged so that guidewire **320** can travel freely therethrough whereas when they are inflated to a certain degree, optionally up to a maximal inflation volume, lumens **332** and **342** decrease in diameter to equal or less than guidewire **320** outer boundaries (as shown in FIG. **9**B) therefore sealing a fluid passage therebetween. In some embodiments, inflatable bodies **331** and **341** include compliant material capable of conforming to guidewire boundaries at certain inner pressures.

Tn some embodiments, a proximal zero seal **352** is provided between fluid inlet **316** and proximal guidewire opening **318**. Optionally and additionally, a distal zero seal **354** is provided between fluid outlet **317** and distal guidewire opening **319**. Zero seals **352** and **354** are normally closed to fluid flow at the absence of a guidewire passing therethrough. FIG. **9**A shows a scenario in which a guidewire is absent from infusion lumen **310**IL yet by delivering a fluid Fin therein through fluid inlet **316** a fluid Fout is delivered out only through fluid outlet **317** and not through guidewire openings **318** and **319** since that zero seals **352** and **354** are closed and sealed to fluid passage therethrough. FIG. **9**B shows another scenario in which guidewire **320** travels through infusion lumen **310**IL and guidewire openings **318** and **319**, forcing zero seals **352** and **354** to open, yet by delivering a fluid Fin in infusion lumen **310**IL it can only be delivered (as fluid Fout) through fluid outlet **317** since that both guidewire seals are inflated and seal fluid passage between them and guidewire **320**.

Reference is now made to FIGS. **10**A-I which illustrate side views and cross section views of an exemplary angioplasty infusion balloon catheter **400** comprising a guidewire based valving mechanism, in accordance with embodiments of the present invention. Balloon catheter **400** includes an elongated shaft **410** connected at its proximal end with a triple connector **420**. An inflatable angioplasty balloon **430** is provided along a portion of its distal end. Shaft **410** encloses an infusion lumen **414** and an inflation lumen **415** separated and sealed to infusion lumen **414** with a wall **413**. Infusion lumen **414** extends along entire length and opened at both ends of catheter **400**, having a proximal guidewire opening **422** and a distal guidewire opening **424**, allowing in size and shape passage in between and therethrough of a guidewire **440**. Infusion lumen **414** also includes a fluid inlet **421** in triple connector **420** distally to proximal guidewire opening **422**. Fluid inlet **421** comprises a single opening and connection means (optionally a luer connection to a syringe) for allowing selective introduction into infusion lumen **414** of at least type of fluid, such as a contrast enhancing medium, flushing fluid (e.g., saline), medicament, chemical or biological compounds, or others. A fluid outlet **412** is provided proximally and close (optionally adjacent) to balloon **430** and allows delivery of fluid outside infusion lumen **414** proximally and adjacent to balloon **430**. Fluid outlet **412** may include a single opening (as shown) or a plurality of openings of any chosen number, form, arrangement or other.

Inflation lumen **415** extends about most of infusion lumen **414** length, between an inflation inlet **423** in triple connector **420**, distally to proximal guidewire opening **422** and in general opposite direction to fluid inlet **421**, and an inflation outlet opened to inner volume of balloon **430**. Inflation inlet **423** comprises a single opening and connection means (optionally a luer connection to a syringe) for allowing selective delivery into or withdrawal from inflation lumen **415** of inflation fluid (optionally saline, optionally with contrast enhancing agent) for inflating and deflating, respectively, balloon **430**.

Infusion lumen **414** includes a proximal segment **409** extending at least partially between proximal guidewire opening **422** and fluid inlet **421**, a distal segment **418** extending at least partially between fluid outlet **412** and distal guidewire opening **424**, and an intermediate segment extending in between proximal segment **409** and distal segment **418**. Proximal segment **409** and distal segment **418** have circular cross sections equal or slightly over cross section of guidewire **440** so that the guidewire can snugly fit therein yet can be passed freely either proximally or distally.

The intermediate segment of infusion lumen **414** has a crescent shaped cross section which encloses a circular area equal or greater than cross section area of guidewire **440**. This way, a fluid can travel freely in infusion lumen **414** intermediate segment from fluid inlet **421** to fluid outlet **412** despite presence of guidewire **440**. Proximal segment **409** adjoins the intermediate segment with a gradual widening **419** and the intermediate segment adjoins distal segment **418** with a gradual narrowing **417**. The close fit of guidewire **440** in proximal segment **409** and distal segment **418** of infusion lumen **414** and substantial lengths thereof (greater than 20 mm, optionally about 50 mm, each) seals (fully or partially) fluid travel therethrough, so that most or all infusion fluid entering infusion lumen **414** through fluid inlet **421** will be delivered through fluid outlet **412** and not through proximal guidewire opening **422** and distal guidewire opening **424**, at least as long as guidewire **440** nests therein and obstructs them.

Balloon **430** includes a non-compliant or semi-compliant inflatable membrane **431** fixated in both ends to shaft **410** outer periphery with a proximal constriction **432** and a distal constriction **433**. An optional soft tip **434** is provided for improving safety to vasculature during delivery. Balloon **430** is configured for dilating a narrowed portion, optionally stenotic, of a blood vessel by inflating it under a moderate to high pressure, according to anatomic location and blood vessel diameter at the treatment location. Inflation lumen **415** being completely sealed to infusion lumen **414** allows an independent applicability of balloon **430** with respect to infusion and fluid delivery through fluid outlet **412**, so that fluid can be delivered if balloon **430** is inflated, deflated or while being in a process of inflation or deflation. Delivering contrast media, agent or medicament proximally to balloon **430** when inflated has some advantages as balloon **430** acts also as an occlusion balloon enabling this way a localized delivery and treatment instead of systemic.

In some embodiments of the present invention, a fluid outlet of a dilatation balloon catheter has a single, substantially large opening. In some embodiments, the total opened area of the opening is equal to or greater than a minimal cross section area of the infusion lumen, in a portion proximal to the opening. Optionally and alternatively, the total opened area is equal or greater than a minimal cross section area of the infusion lumen, in a portion proximal to the opening less a cross section area of a guidewire of a minimally allowed diameter, or of a maximally allowed diameter, or an intermediate value. In some embodiments, total opened area of fluid outlet is at least 0.5 mm^2, optionally at least 1 mm^2, optionally at least 2 mm^2, optionally at least 5 mm^2, optionally about 1.2 mm^2, optionally about 2.5 mm^2 or higher, or lower, or an intermediate value. One advantage of a substantially large single opening, rather than a plurality of smaller openings, is the possibility to inject fluids in equal or greater rates without causing jets from the fluid outlet. In some embodiments, in order to prevent a possible deformation (e.g., a kinking, a bending, a twisting, or a combination thereof, or other) and/or deterioration the catheter shaft adjacent the opening, due to the possible increased weakening made by a substantially large single opening, a structural fortification is added to the catheter shaft about the opening. FIGS. **13**, **14** and **15** disclose three exemplary types of fortifications.

The device illustrated in FIGS. **10**A-**10**I is made according to the principles illustrated schematically in FIG. **7**A. As noted above, it is advantageous for the lengths of the narrowed portions of the infusion lumen at the proximal and distal portions of the catheter (designated **113** and **115** in FIG. **7**A) to be 20 mm long or more, and also for the infusion opening positioned proximal to the balloon (designated **117** in FIG. **7**A) to be a single opening having a cross sectional area equal to or greater than the minimal cross sectional area of the infusion lumen in between the narrowed portions minus the cross sectional area of the largest diameter allowed guidewire. The cross sectional area of the largest diameter allowed guidewire is approximately equal to the cross sectional area of at least the distal narrowed portion of the infusion lumen. The cross sectional area of the infusion opening can thus be expressed as equal to or greater than the minimal cross sectional area of the larger cross section portion of the infusion lumen between the narrowed portions (designated **111** in FIG. **7**A), and the minimal cross sectional area of the distal narrowed portion of the infusion lumen. This implementation has the significant advantage that the relatively long lengths of the narrowed portions of the infusion lumen substantially seal the ends of the infusion lumen in the presence of the guidewire without the use of additional valving or clamping structures that complicate device construction, and the relatively large infusion opening provides a high volume outflow of infusate. This remains true even when the nesting of the guidewire in the narrowed portions of the infusion lumen is loose enough to allow easy sliding of the catheter structure over the guidewire.

FIGS. **13**A-B schematically illustrate cut views of an exemplary balloon catheter **500** with a single proximal fluid outlet **512** comprising a first exemplary fortification, in accordance with embodiments of the present invention. Balloon catheter **500** shown with its distal end includes an elongated shaft **510** and an inflatable angioplasty balloon **530** that is provided along a portion of its distal end. Shaft **510** encloses an infusion lumen **514** and an inflation lumen **515** separated and sealed to infusion lumen **514** with a wall **513**. Inflation lumen **515** being completely sealed to infusion lumen **514** allows an independent applicability of balloon **530**, so that fluid can be delivered if balloon **530** is inflated, deflated or while being in a process of inflation or deflation.

Infusion lumen **514** includes a distal guidewire opening **524** allowing passage therethrough of a guidewire (not shown) optionally one of several possibly prescribed guidewires. A fluid outlet **512** is provided proximally and close (optionally adjacent) to balloon **530** and allows delivery of fluid outside infusion lumen **514** proximally and adjacent to balloon **530**. Infusion lumen **514** narrows with a gradual narrowing **517** into a distal segment **518**. Until narrowing **517**, infusion lumen **514** has a crescent shaped cross section which encloses a circular area equal or greater than cross section area of a guidewire with a maximally allowed diameter. Distal segment **518** has circular cross sections equal or slightly over cross section of said guidewire so that the guidewire can snugly fit therein yet can be passed freely either proximally or distally. Infusion lumen **514** is configured such that most or all infusion fluid entering therein will be delivered through fluid outlet **512** and not through distal guidewire opening **524**, at least as long a prescribed guidewire nests therein and obstructs distal segment **518** and distal guidewire opening **524**.

Fluid outlet **512** has a single, substantially large opening with a total opened area being equal to or greater than the cross section area of infusion lumen **514** proximal to fluid outlet **512** less a cross section area of a guidewire with a minimal prescribed diameter. The portion of shaft **510** about fluid outlet **512** is fortified with a mesh patch **545** optionally made from stainless steel in a rectangular shape curved to nest over shaft **510**. In some embodiments, the total opened area of fluid outlet **512** is calculated as the total area covered by the outline of fluid outlet **512** less the area covered by mesh **545** above fluid outlet **512**. Mesh patch **545** is fixated to shaft **510** with a cover such as a flexible sleeve **540**, optionally made from nylon, with a hole cut thereto enclosing fluid outlet **512**. Therefore, fluid delivered through fluid outlet **512** will pass then through the portion of mesh insert **545** thereabove and then through the hole in sleeve **540**.

FIGS. **14**A-B schematically illustrate cut views of an exemplary balloon catheter **600** with a single proximal fluid outlet **612** comprising a second exemplary fortification, in accordance with embodiments of the present invention. Balloon catheter **600** shown with its distal end includes an elongated shaft **610** and an inflatable angioplasty balloon **630** that is provided along a portion of its distal end. Shaft **610** encloses an infusion lumen **614** and an inflation lumen **615** separated and sealed to infusion lumen **614** with a wall **613**. Inflation lumen **615** being completely sealed to infusion lumen **614** allows an independent applicability of balloon **630**, so that fluid can be delivered if balloon **630** is inflated, deflated or while being in a process of inflation or deflation.

Infusion lumen **614** includes a distal guidewire opening **624** allowing passage therethrough of a guidewire (not shown) optionally one of several possibly prescribed guidewires. A fluid outlet **612** is provided proximally and close (optionally adjacent) to balloon **630** and allows delivery of fluid outside infusion lumen **614** proximally and adjacent to balloon **630**. Infusion lumen **614** narrows with a gradual narrowing **617** into a distal segment **618**. Until narrowing **617**, infusion lumen **614** has a crescent shaped cross section which encloses a circular area equal or greater than cross section area of a guidewire with a maximally allowed diameter. Distal segment **618** has circular cross sections equal or slightly over cross section of said guidewire so that the guidewire can snugly fit therein yet can be passed freely either proximally or distally. Infusion lumen **614** is configured such that most or all infusion fluid entering therein will be delivered through fluid outlet **612** and not through distal guidewire opening **624**, at least as long a prescribed guidewire nests therein and obstructs distal segment **618** and distal guidewire opening **624**.

Fluid outlet **612** has a single, substantially large opening with a total opened area being equal to or greater than the cross section area of infusion lumen **614** proximal to fluid outlet **612** less a cross section area of a guidewire with a minimal prescribed diameter. The portion of shaft **610** about fluid outlet **612** is fortified with a tube insert **640** optionally made from stainless steel and having an internal diameter equal or greater than a maximally allowed guidewire diameter, and an outer diameter equal or smaller than a circle enclosed in infusion lumen **614** between wall **613** and shaft **610**. Tube insert **640** is fixated to shaft **610** optionally by soldering or gluing, or it may be freely disposed therein, optionally in a snug fit. Tube insert **640** includes a hole positioned such to enclose fluid outlet **612**. Therefore, fluid delivered through fluid outlet **612** will pass first through the hole in tube insert **640**.

FIGS. **15**A-B schematically illustrate cut views of an exemplary balloon catheter **700** with a single proximal fluid outlet **712** comprising a third exemplary fortification, in accordance with embodiments of the present invention. Balloon catheter **700** shown with its distal end includes an elongated shaft **710** and an inflatable angioplasty balloon **730** that is provided along a portion of its distal end. Shaft **710** encloses an infusion lumen **714** and an inflation lumen **715** separated and sealed to infusion lumen **714** with a wall **713**. Inflation lumen **715** being completely sealed to infusion lumen **714** allows an independent applicability of balloon **730**, so that fluid can be delivered if balloon **730** is inflated, deflated or while being in a process of inflation or deflation.

Infusion lumen **714** includes a distal guidewire opening **724** allowing passage therethrough of a guidewire (not shown) optionally one of several possibly prescribed guidewires. A fluid outlet **712** is provided proximally and close (optionally adjacent) to balloon **730** and allows delivery of fluid outside infusion lumen **714** proximally and adjacent to balloon **730**. Infusion lumen **714** narrows with a gradual narrowing **717** into a distal segment **718**. Until narrowing **717**, infusion lumen **714** has a crescent shaped cross section which encloses a circular area equal or greater than cross section area of a guidewire with a maximally allowed diameter. Distal segment **718** has circular cross sections equal or slightly over cross section of said guidewire so that the guidewire can snugly fit therein yet can be passed freely either proximally or distally. Infusion lumen **714** is configured such that most or all infusion fluid entering therein will be delivered through fluid outlet **712** and not through distal guidewire opening **724**, at least as long a prescribed guidewire nests therein and obstructs distal segment **718** and distal guidewire opening **724**.

Fluid outlet **712** has a single, substantially large opening with a total opened area being equal to or greater than the cross section area of infusion lumen **714** proximal to fluid outlet **712** less a cross section area of a guidewire with a minimal prescribed diameter. The portion of shaft **710** about fluid outlet **712** is fortified with a sheet insert **740** optionally made from stainless steel in a rectangular shape curved to nest in shaft **710**. Sheet insert **740** is fixated to shaft **710** optionally by soldering or gluing, or optionally the fortified portion and/or sheet insert **740** is deformed resulting in a tight fit. Tube insert **740** includes a hole positioned such to enclose fluid outlet **712**. Therefore, fluid delivered through fluid outlet **712** will pass first through the hole in tube insert **740**.

The following table show exemplary not binding parameters for dilatation balloon catheter according to the present invention, separated according to indication (i.e., a specific anatomic location and/or blood vessel type in need for dilatation and/or revascularization).

TABLE 1

Exemplary sizes and indications of balloon catheters

Indication	Balloon diameter and length (mm)	Catheter length (cm)	Sheath size (F)	Dilatation pressures: nominal and RPB (Atm)	Guidewire size (Inches)
PTA catheter for Treating AV fistula or graft	D: 5-12 L: 20/40/60/80	50/80/135	6/7/8	Nom.: 8 RPB: 18-30	0.035

TABLE 1-continued

Exemplary sizes and indications of balloon catheters

Indication	Balloon diameter and length (mm)	Catheter length (cm)	Sheath size (F)	Dilatation pressures: nominal and RPB (Atm)	Guidewire size (Inches)
PTA catheter for treating large blood vessels	D: 14-18 L: 20/40/60	80/120	8	Nom.: 8 RPB: 10-12	0.035
PTA catheter for treating peripheral blood vessels	D: 4-9 L: 20-200	80/135	5-8	Nom.: 6-8 RPB: 10-15	0.018/0.035
PTA catheter for treating coronary blood vessels	D: 1.5-4 L: 8-40	140	5	Nom.: 6 RPB: 14	0.014
Embolectomy catheter	D: 4-15	40/80	4-8		0.02.5/0.035

It is to be fully understood that certain aspects, characteristics, and features, of the invention, which are, for clarity, illustratively described and presented in the context or format of a plurality of separate embodiments, may also be illustratively described and presented in any suitable combination or sub-combination in the context or format of a single embodiment. Conversely, various aspects, characteristics, and features, of the invention which are illustratively described and presented in combination or sub-combination in the context or format of a single embodiment, may also be illustratively described and presented in the context or format of a plurality of separate embodiments.

Although the invention has been illustratively described and presented by way of specific exemplary embodiments, and examples thereof, it is evident that many alternatives, modifications, or/and variations, thereof, will be apparent to those skilled in the art. Accordingly, it is intended that all such alternatives, modifications, or/and variations, are encompassed by the broad scope of the appended claims.

All publications, patents, and or/and patent applications, cited or referred to in this disclosure are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent, or/and patent application, was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this specification shall not be construed or understood as an admission that such reference represents or corresponds to prior art of the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting.

What is claimed is:

1. An infusion catheter comprising:

a shaft comprising a proximal section, a distal section, and an intermediate section therebetween;

a first lumen and a second lumen extending along a length of the shaft; and

an inflatable member provided distally to the intermediate section, and over the distal section;

wherein the first lumen has a cross section larger than a cross section of the second lumen and is configured to receive a guidewire therethrough and to allow fluid flow via an unobstructed portion of the first lumen,

wherein the unobstructed portion is formed along an outer surface of the guidewire, between the outer surface of the guidewire and an inner wall of the first lumen, and extends from an infusion inlet at a proximal end of the intermediate section to an infusion outlet at a distal end of the intermediate section;

wherein the first lumen is narrowed to approximate a first diameter in the proximal section and along an entire length of the distal section, and is widened to approximate a second diameter greater than the first diameter in the intermediate section, and

wherein the infusion inlet is located in a proximal connector that is configured to allow selective introduction of a fluid into the first lumen.

2. The infusion catheter of claim **1**, wherein the second lumen extends from an inflation inlet to an inflation outlet,

wherein the inflation inlet is located in the proximal connector;

wherein the inflation outlet opens to an inner volume of the inflatable member.

3. The infusion catheter of claim **2**, wherein the inflation inlet and the inflation outlet are different from the infusion inlet and the infusion outlet.

4. The infusion catheter of claim **1**, wherein a proximal guidewire opening is located in the proximal connector and a distal guidewire opening is located in the distal section of the shaft, wherein the proximal guidewire opening and the distal guidewire opening are configured to allow passage of the guidewire.

5. The infusion catheter of claim **4**, wherein the proximal guidewire opening and the distal guidewire opening are different from the infusion inlet and the infusion outlet.

6. The infusion catheter of claim **1**, wherein:

an inflation inlet is located in the proximal connector,

an inflation outlet opens to an inner volume of the inflatable member,

wherein the second lumen extends from the inflation inlet to the inflation outlet;

a proximal guidewire opening is located in the proximal connector, and

a distal guidewire opening is located in the distal section of the shaft,

wherein the proximal guidewire opening and the distal guidewire opening are configured to allow passage of the guidewire.

7. The infusion catheter of claim **6**, wherein the inflation inlet and the inflation outlet are different from the infusion inlet and the infusion outlet.

8. The infusion catheter of claim **7**, wherein the proximal guidewire opening and the distal guidewire opening are different from the infusion inlet and the infusion outlet.

9. The infusion catheter of claim 8, wherein the inflation inlet and the inflation outlet are different from the proximal guidewire opening and the distal guidewire opening.

10. The infusion catheter of claim 1, wherein said second lumen has an oval shaped cross section, and wherein said first lumen has a crescent shaped cross section.

11. The infusion catheter of claim 1, wherein said second lumen has a lens shaped cross section, and wherein said first lumen has a crescent shaped cross section.

12. The infusion catheter of claim 1, wherein the first diameter of the first lumen is sized such that the guidewire obstructs fluid flow in the proximal section and in the distal section.

13. The infusion catheter of claim 1, wherein the guidewire has an outer diameter of about the first diameter.

14. The infusion catheter of claim 1, wherein a section of the first lumen is reinforced around and in proximity to the infusion outlet with a metal sheet insert fixedly laid on the inner wall of the first lumen.

15. The infusion catheter of claim 1, wherein the infusion outlet is located adjacent to the inflatable member.

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